

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UFCW LOCAL 1500 WELFARE FUND, on behalf
of itself and all others similarly situated,

Plaintiff,

v.

ACTAVIS HOLDCO U.S., INC., FOUGERA
PHARMACEUTICALS INC., SANDOZ, INC.,
TEVA PHARMACEUTICALS USA INC., and
TARO PHARMACEUTICALS U.S.A., INC.,

Defendants.

No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

1. Plaintiff UFCW Local 1500 Welfare Fund, on behalf of itself and all others similarly situated, brings this class action for claims under federal and state antitrust laws to recover damages and obtain injunctive and equitable relief for the substantial injuries it and others similarly situated have sustained against Defendants arising from their conspiracy to raise the prices of and allocate markets and customers for fluocinonide topical cream (0.05%), cream with emulsified base (0.05%), gel (0.05%), and ointment (0.05%) products (collectively, “fluocinonide”) in the United States. Plaintiff’s claims arise from a set of conspiracies by numerous generic drug manufacturers, including Defendants here, to unlawfully raise the prices of more than a dozen generic drugs, including those at issue in this Complaint. Plaintiff’s allegations are made on personal knowledge as to Plaintiff and Plaintiff’s own acts and upon information and belief as to all other matters.

NATURE OF THE ACTION

2. Fluocinonide is a commonly prescribed medication used to treat skin conditions such as dermatitis and psoriasis. Significantly, this drug is not new: fluocinonide was introduced in the 1970s and has thus been on the market for over 40 years under various brand names.

3. Generic versions of fluocinonide have also been on the market for years and, for most of that time, have been priced significantly lower than their branded counterparts—in many instances priced at less than a dollar per gram. This is because the presence of generic drugs usually results in vigorous price competition, benefiting consumers and third-party payors through lower prices.

4. Recently, however, fluocinonide has experienced unprecedented price increases. Indeed, since the third quarter of 2014, the price of certain fluocinonide formulations has increased **over 200%**. The U.S. Government Accountability Office (“GAO”) also noted that fluocinonide had experienced “extraordinary price increases” between 2010 and 2015.¹

5. Fluocinonide’s price hikes, however, were not the result of competitive market forces; instead, they were the result of Defendants’ conspiracy to fix, raise, maintain, and stabilize the prices of, as well as allocate customers and markets for, fluocinonide.

6. Defendants orchestrated their conspiracy through secret communications and meetings, both in private and at public events, such as trade association meetings held by the Generic Pharmaceutical Association (“GPhA”), among others. Oligopolistic conditions—*e.g.*, low numbers of competitors and barriers to entry in the market for fluocinonide—facilitated Defendants’ anticompetitive actions and have allowed them to sustain their unlawful supracompetitive pricing to the present.

¹ See GAO, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, No. 16-706, App’x III (Aug. 2016), <http://www.gao.gov/assets/680/679022.pdf>.

7. Defendants' price increases have also grabbed the attention of government enforcers, members of Congress, the press, and drug purchasers. The Department of Justice's Antitrust Division ("DOJ") and the Connecticut Attorney General's Office ("CTAG")—which is leading a multi-state working group of state attorneys general—are conducting sweeping antitrust probes into allegations that as many as a dozen generic drug manufacturers participated in a broad-based conspiracy to fix, raise, maintain, and stabilize the prices of as many as two-dozen generic drugs. Significantly, DOJ has issued subpoenas which arise from a federal grand jury proceeding in the Eastern District of Pennsylvania that is investigating whether Defendants and other drug manufacturers conspired to fix generic drug prices.

8. For example, in September 2016, Taro, which manufactures fluocinonide, disclosed that it, "as well as two senior officers in its commercial team, received grand jury subpoenas from the [DOJ]," seeking, among other things, "communications with competitors and others regarding the sale of generic pharmaceutical products."² Actavis and Teva have received similar subpoenas from DOJ.

9. The government investigations into generic drug manufacturers' pricing behavior go beyond just fluocinonide. DOJ and CTAG have issued subpoenas seeking information about their pricing of multiple other generic products to several other generic drug manufacturers including: Impax, Lannett, Par, Actavis, Mayne Pharma, Mylan, Teva, and Zydus.

10. On December 13, 2016, the DOJ filed its first criminal charges against two former executives of Heritage Pharmaceuticals: Jeffrey Glazer and Jason Malek.³ DOJ alleged that both

² Taro, SEC Form 6-K (Sept. 9, 2016), <http://phx.corporate-ir.net/phoenix.zhtml?c=114698&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTExMTM0MjUwJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVEIPT9FTIRJkUmc3Vic2lkPTU3>.

³ *United States v. Malek*, No. 16-cr-508 (E.D. Pa., Dec. 13, 2016); *United States v. Glazer*, No. 16-cr-506 (E.D. Pa., Dec. 13, 2016).

Glazer and Malek conspired with others “to allocate customers, rig bids, and fix and maintain prices” of doxycycline and glyburide sold in the United States. Each was charged with two felony counts under the Sherman Act (15 U.S.C. §1).

11. The next day, 20 state attorneys general also sued Aurobindo Pharma, Citron Pharma, Heritage Pharmaceuticals, Mayne Pharma, Mylan, and Teva for bid-rigging, price-fixing and customer allocation in connection with their sale of doxycycline and glyburide in the United States.⁴

12. The DOJ investigation could also result in the imposition of substantial fines against many generic drug manufacturers, including those named as Defendants here. One analyst has estimated, for example, that Teva could face liability of between \$300 million and \$700 million, while Mylan could face liability of between \$380 million and \$770 million. Another analyst estimated that fines industry-wide could exceed \$1 billion.⁵

13. In addition to DOJ’s and CTAG’s investigations, members of Congress have written letters to generic manufacturers Actavis, Apotex, Impax, Lannett, Mylan, Par, Sun, Teva, West-Ward, and Zydus, requesting information concerning their sales of numerous generic drugs, including albuterol sulfate, glycopyrrolate, neostigmine methylsulfate, and benazepril/hydrochlorothiazide.

14. Defendants’ scheme here was no different than the wrongdoing complained of by DOJ and the state attorneys general. Nor were defendants’ motivations different: Defendants here, like the defendants in DOJ’s and the state attorneys’ general complaints, sought to reduce competition and extract supracompetitive prices at the expense of U.S. consumers. As a result of

⁴ *Connecticut v. Aurobindo Pharma USA, Inc.*, No. 16-cv-02056 (D. Conn., Dec. 15, 2016).

⁵ Eric Sagonowsky, *DOJ’s price-fixing investigation could lead to sizable liabilities, analyst says*, FiercePharma (Nov. 10, 2016), <http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says>.

Defendants' scheme to rig bids, fix and maintain prices for, and allocate customers of, fluocinonide, consumers and third-party payors paid, and continue to pay, supracompetitive prices for these generic drugs.

15. Plaintiff seeks to certify two classes. The first class (the "Injunctive Class") is composed of all individuals and entities in the United States or its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for fluocinonide, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as August 1, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased (the "Class Period").

16. The second class (the "Damages Class") is composed of all individuals and entities who, in Alabama, Arizona, California, Florida, Hawaii, Iowa, Kansas, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia, indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for fluocinonide, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as August 1, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

JURISDICTION AND VENUE

17. Plaintiff brings this action under Section 16 of the Clayton Act, 15 U.S.C. §26, to obtain injunctive relief and costs of suit, including attorneys' fees, against Defendants for the injuries that Plaintiff and the other members of the Injunctive Class have suffered from Defendants' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

18. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 and Section 16 of the Clayton Act, 15 U.S.C. § 26, because this action arises under the federal antitrust laws. This Court also has supplemental jurisdiction over state law claims pursuant to 28 U.S.C. § 1367(a).

19. This Court also has jurisdiction over this matter under 28 U.S.C. § 1332(d) because this action is a class action in which the aggregate amount in controversy for the proposed class exceeds \$5,000,000 and at least one member of the Damages Class is a citizen of a state different from that of one of Defendants.

20. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), and (d) and Section 12 of the Clayton Act, 15 U.S.C. § 22, because Defendants resided, transacted business, were found, or had agents within this District, and a portion of the affected interstate trade and commerce discussed below was carried out in this District.

21. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

22. Defendants sold and shipped fluocinonide in a continuous and uninterrupted flow of interstate commerce. The conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate and intrastate commerce.

23. Each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their conspiracy.

THE PARTIES

A. Plaintiff

24. Plaintiff UFCW Local 1500 Welfare Fund ("**Local 1500**") is an employee welfare benefits fund with its principal place of business at 425 Merrick Avenue, Westbury, New York,

11590. Local 1500 provides nearly 23,000 members with health and welfare benefits, many of whom live in New York, among other states. During the Class Period, Local 1500 purchased and paid for some or all the purchase price for fluocinonide, thereby suffering injury to its business and property. Local 1500 paid and reimbursed more for these products than it would have absent Defendants' anticompetitive conduct to fix, raise, maintain, and stabilize the prices and allocate markets and customers.

B. Defendants

1. Actavis

25. Defendant Actavis Holdco U.S., Inc. ("**Actavis**") is a corporation with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. In August 2016, Teva Pharmaceuticals U.S., Inc. acquired Actavis from Allergan plc's for \$40.5 billion. In connection with this acquisition, Allergan assigned certain assets of its "generics business" to Actavis, so that by acquiring Actavis, Teva also acquired Allergan's generics business. Actavis manufactures, markets, and sells generic drug products.

26. Actavis partnered with G&W Laboratories, Inc., whereby G&W Laboratories manufactured fluocinonide that Actavis distributed under its own trade dress. During the Class Period, Actavis sold generic fluocinonide in the United States.

2. Sandoz Defendants

27. Defendant Sandoz, Inc. is a Colorado corporation with its principal place of business located at 100 College Road, Princeton, New Jersey, 08540. Sandoz, Inc. is a global leader in generic pharmaceuticals and biosimilars and is a division of the Novartis Group.

28. Defendant Fougera Pharmaceuticals Inc. is a New York corporation with its principal place of business located at 60 Baylis Road, Melville, New York, 11747. Fougera is a

wholly-owned subsidiary of Sandoz, Inc., specializing in the production, marketing, and sale of dermatological products.

29. Defendants Sandoz, Inc. and Fougera Pharmaceuticals Inc. are collectively referred to as “**Sandoz**.” Sandoz manufactures, markets, and sells generic pharmaceutical products in the United States. During the Class Period, Sandoz sold generic fluocinonide in the United States.

3. Taro

30. Defendant Taro Pharmaceuticals U.S.A., Inc. (“**Taro**”) is a corporation with its principal place of business at Three Skyline Drive, Hawthorne, New York 10532. Taro is a subsidiary of Taro Pharmaceuticals Industries Ltd., an Israeli company with its principal place of business at 14 Hakitor Street, PO Box 10347, Haifa Bay, 2624761, Israel. Taro Pharmaceuticals Ltd., in turn, is a subsidiary of Sun Pharma. Taro manufactures, markets, and sells branded and generic pharmaceutical products. During the Class Period, Taro sold generic fluocinonide in the United States.

4. Teva

31. Defendant Teva Pharmaceuticals USA, Inc. (“**Teva**”) is a Pennsylvania-based corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva is a subsidiary of Teva Pharmaceutical Industries Limited, an Israeli company with principal place of business located at 5 Basel Street, Petach Tikva, Israel 49131. Teva manufactures, markets, and sells various generic pharmaceutical products. During the Class Period, Teva manufactured and sold generic fluocinonide in the United States.

32. Defendants Actavis, Sandoz, Taro, and Teva are referred to collectively as “**Defendants**.”

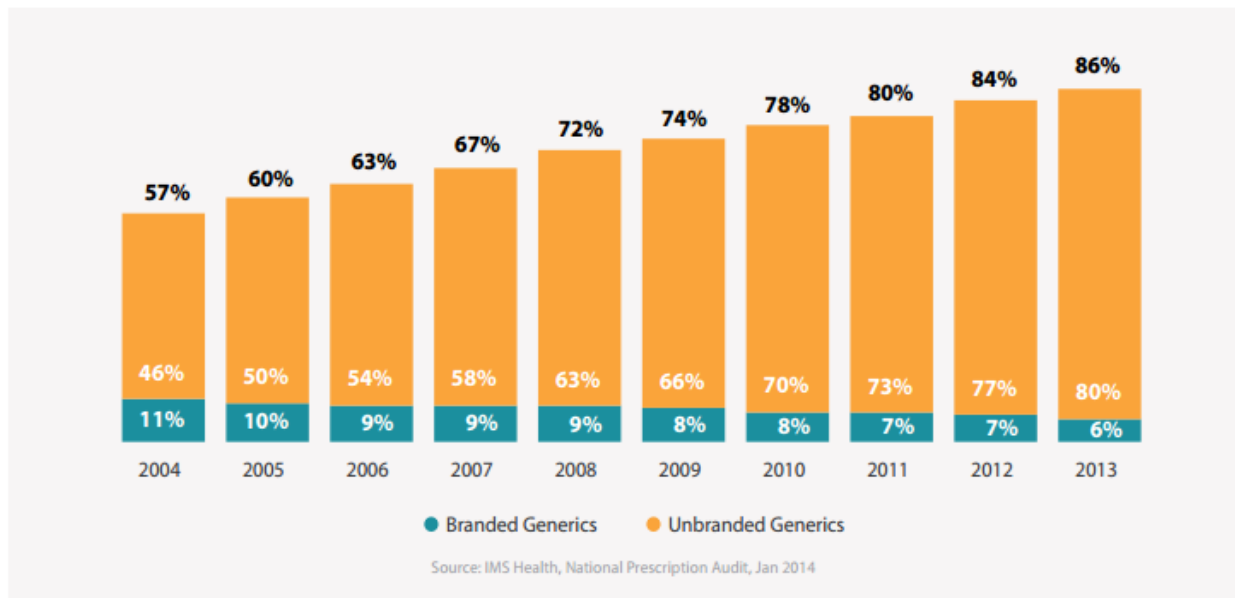
33. Various other entities and individuals unknown to Plaintiff at this time participated as co-conspirators in the acts complained of, and performed acts and made statements that aided and abetted and were in furtherance of the unlawful conduct alleged herein.

**GENERIC DRUGS REDUCE PRESCRIPTION DRUG COSTS
TO PATIENTS AND THIRD-PARTY PAYORS**

34. When generic versions of a branded drug—whether a generic manufactured and sold by an independent generic manufacturer or an “authorized generic,” or “branded generic,” sold by or pursuant to an agreement with the branded manufacturer—enter the market, they quickly gain substantial market share.

35. Empirical studies have shown that within a year of generic entry, generics typically will have obtained about 90% of the market, *i.e.*, pharmacists will fill 90 of every 100 prescriptions with a generic. Indeed, according to IMS Health data, generic drugs as a whole have increased the share of total prescriptions steadily since 2004, and as of 2013, account for 86% of all drugs dispensed in the United States.⁶

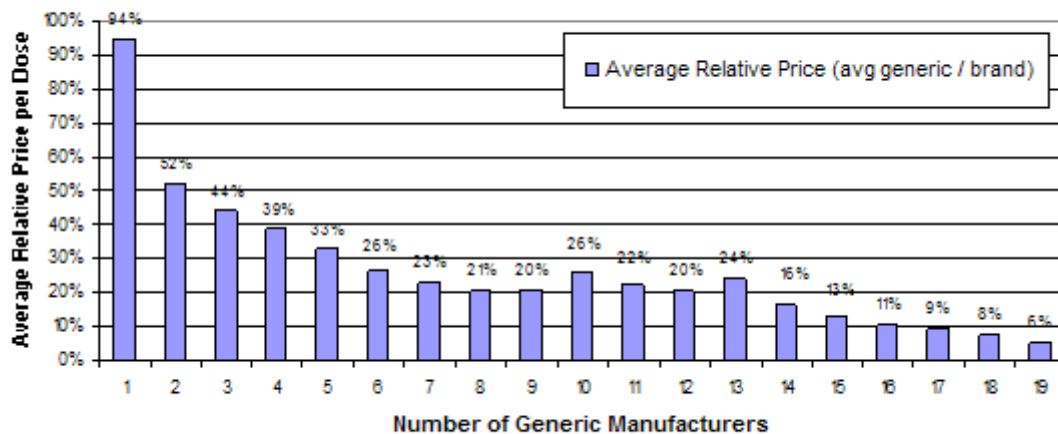
⁶ IMS Institute for Healthcare Informatics, Medicine use and shifting costs of healthcare: A review of the use of medicines in the United States in 2013 (Apr. 2014), at 51, http://www.plannedparenthoodadvocate.org/2014/IIHI_US_Use_of_Meds_for_2013.pdf.

Percent share of prescriptions

36. When generic drugs are launched, they are typically priced below the prices of their branded counterparts. Indeed, in a competitive market, each successive generic product that enters the market lowers the prices of all similar generic products because each entry increases competition for sales and market share. A Food and Drug Administration (“FDA”) study demonstrates this effect in the following chart:⁷

⁷ FDA, Generic Competition and Drug Prices, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

Generic Competition and Drug Prices



Source: FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective (TM), 1999-2004, extracted February 2005

37. More recent evidence obtained by the GAO suggests that each subsequent generic entrant drives the price down by 20%.

38. A Federal Trade Commission study confirmed the FDA's analyses, finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."⁸

39. Thus, generic competition to even a single brand drug can potentially provide billions of dollars in savings to consumers, pharmacies, and other drug purchasers, as well as to private health insurers, health and welfare funds, and state Medicaid programs, which reimburse the cost of drug purchases by covered individuals. Indeed, one study found that the use of generic medicines saved the U.S. healthcare system \$254 billion in 2014 alone, and \$1.68 trillion between 2005 and 2014.⁹

⁸ FTC Staff Study, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), available at <http://emmanuelcombe.org/delay.pdf>.

⁹ Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

40. These consumer welfare-enhancing attributes of generic drug competition were bolstered by the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the “Hatch-Waxman Act.” The Hatch-Waxman Act simplifies the regulatory hurdles that generic drug manufacturers have to clear prior to marketing and selling generic drugs. Instead of filing a lengthy and costly New Drug Application (“NDA”), the Hatch-Waxman Act allows generic drug manufacturers to obtain FDA approval in an expedited fashion through the filing of an Abbreviated New Drug Application (“ANDA”).

41. If an ANDA applicant shows that the generic drug is bioequivalent to the brand drug, then the ANDA applicant may rely on scientific and other data compiled in the brand drug’s NDA, including safety and efficacy data. The ability to rely on the scientific data published in the referenced brand drug’s NDA obviates the need for duplicative and expensive experimentation and clinical trials. The FDA must approve an ANDA unless the information submitted in the ANDA is insufficient to meet the requirements under the Hatch-Waxman Act.

42. In connection with the approval of a generic drug, the FDA will assign a “Therapeutic Equivalence Code” ranging from “AA” to “BX.” An “AB” rating signifies that the approved generic product is therapeutically equivalent to its branded counterpart. An AB rating is significant because under state generic drug substitution laws, pharmacists are permitted—and, in many cases, must—substitute the branded product for its cheaper generic counterpart. Moreover, in about 20 states, non-AB rated generic drugs can be substituted for their branded counterparts subject to certain considerations, including informed consent from patient or

physician and whether the switch is appropriate in a pharmacist's professional judgment.¹⁰ This inures to the financial benefit of consumers and third-party payors.

43. In sum, the streamlined approval process under the Hatch-Waxman Act makes it easier for generic drug manufacturers to bring competing and cheaper generic products to market.

FACTUAL BACKGROUND FOR FLUOCINONIDE

44. Fluocinonide is a potent corticosteroid (Class 2/3) used to treat numerous skin conditions, including dermatitis and psoriasis. It has been marketed since the 1970s. Branded versions of fluocinonide have been marketed in at least four formulations: topical cream, cream with emulsified base, gel, and ointment. Current branded versions of fluocinonide include Lidex® and Lidex-E®.

45. The generic fluocinonide market is characterized by limited competition, with only a handful of companies currently manufacturing the drug, including Defendants Actavis, Sandoz, Taro, and Teva.

(a) Actavis manufactures, markets, and sells generic versions of fluocinonide topical cream.

(b) Sandoz manufactures, markets, and sells generic versions of fluocinonide topical cream, gel, and ointment.

(c) Taro manufactures, markets, and sells generic versions of fluocinonide topical cream, cream with emulsified base, gel, and ointment.

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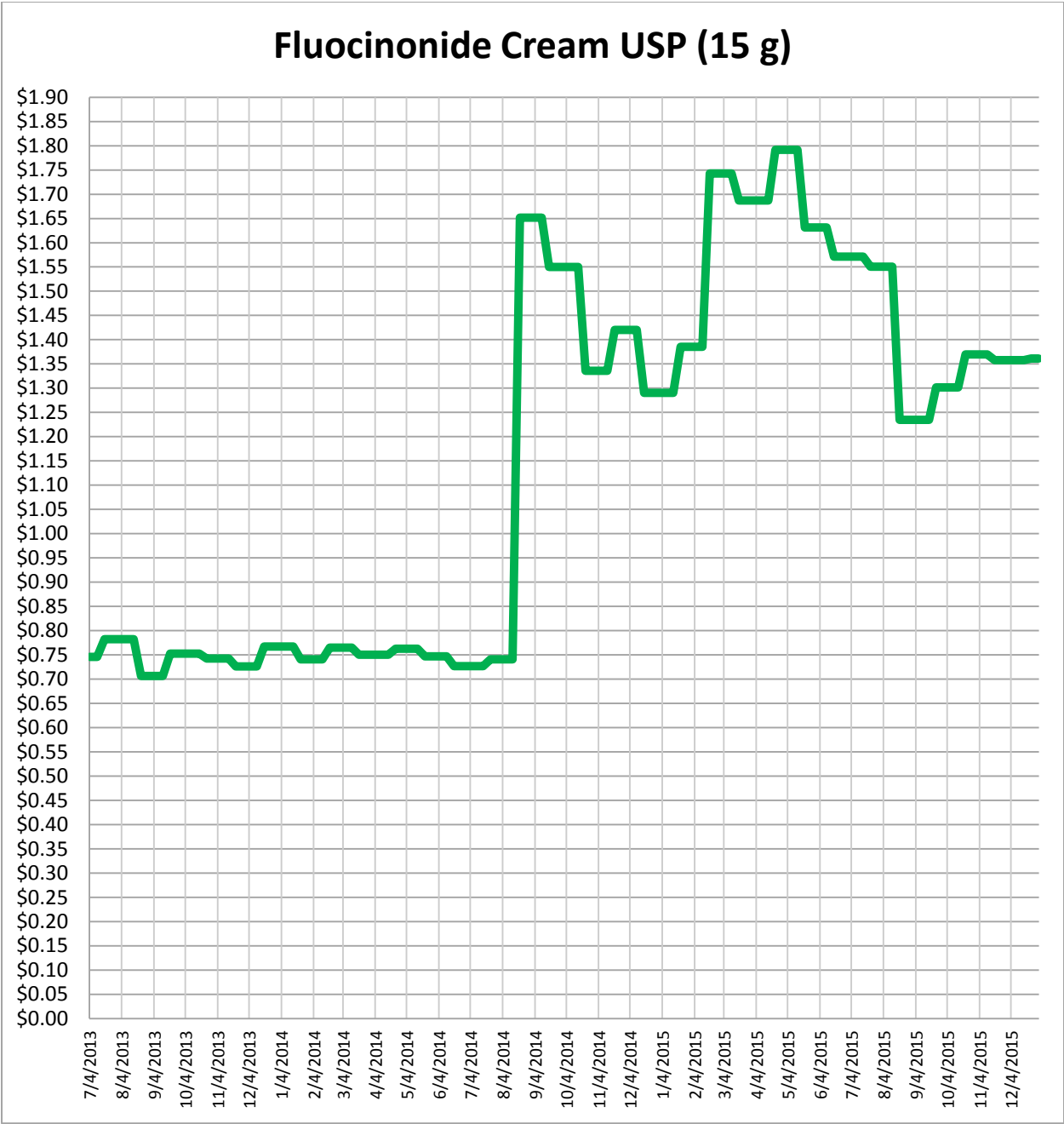
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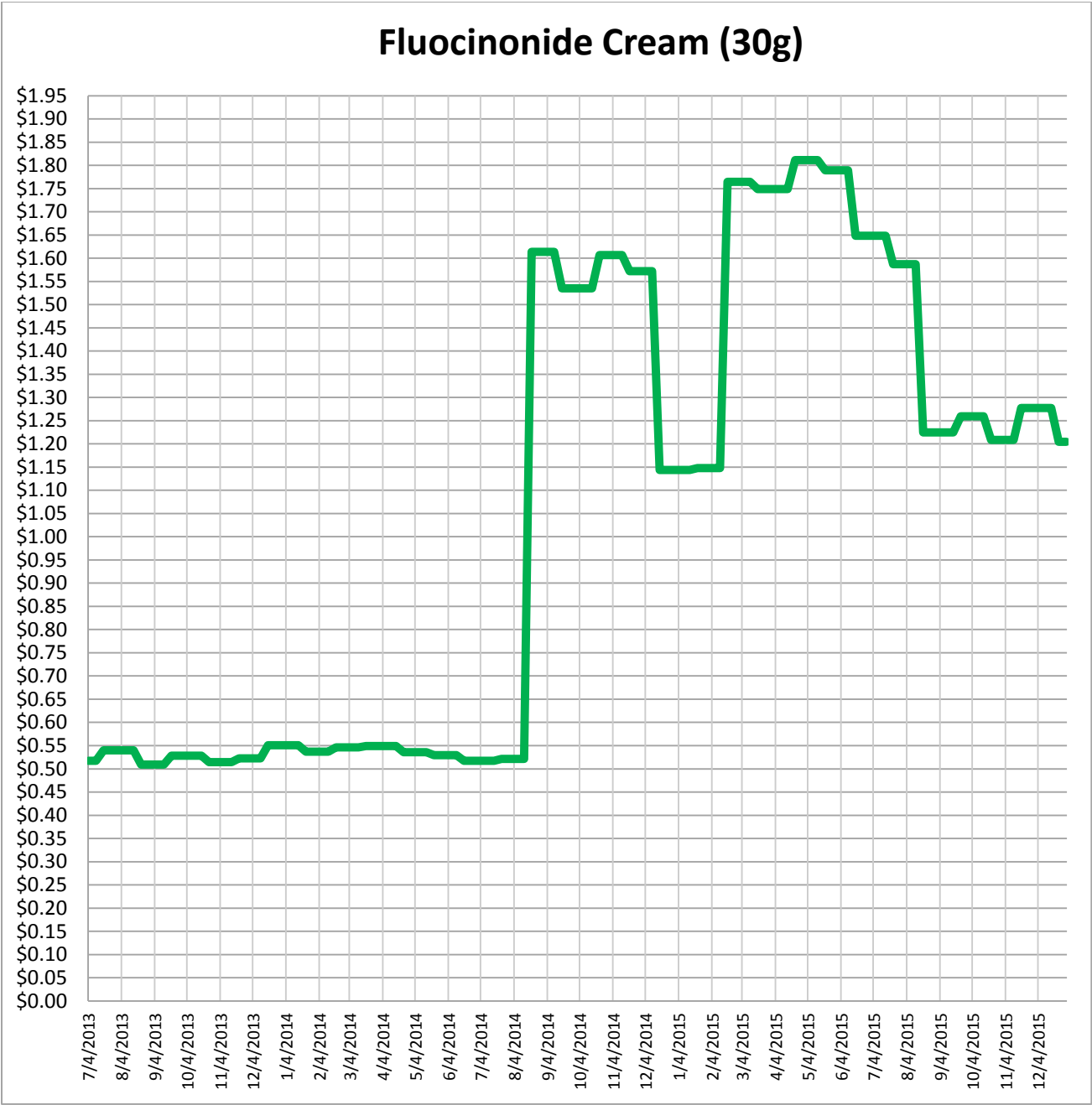
(d) Teva manufactures, markets, and sells generic versions of fluocinonide topical cream, cream with emulsified base, gel, and ointment.

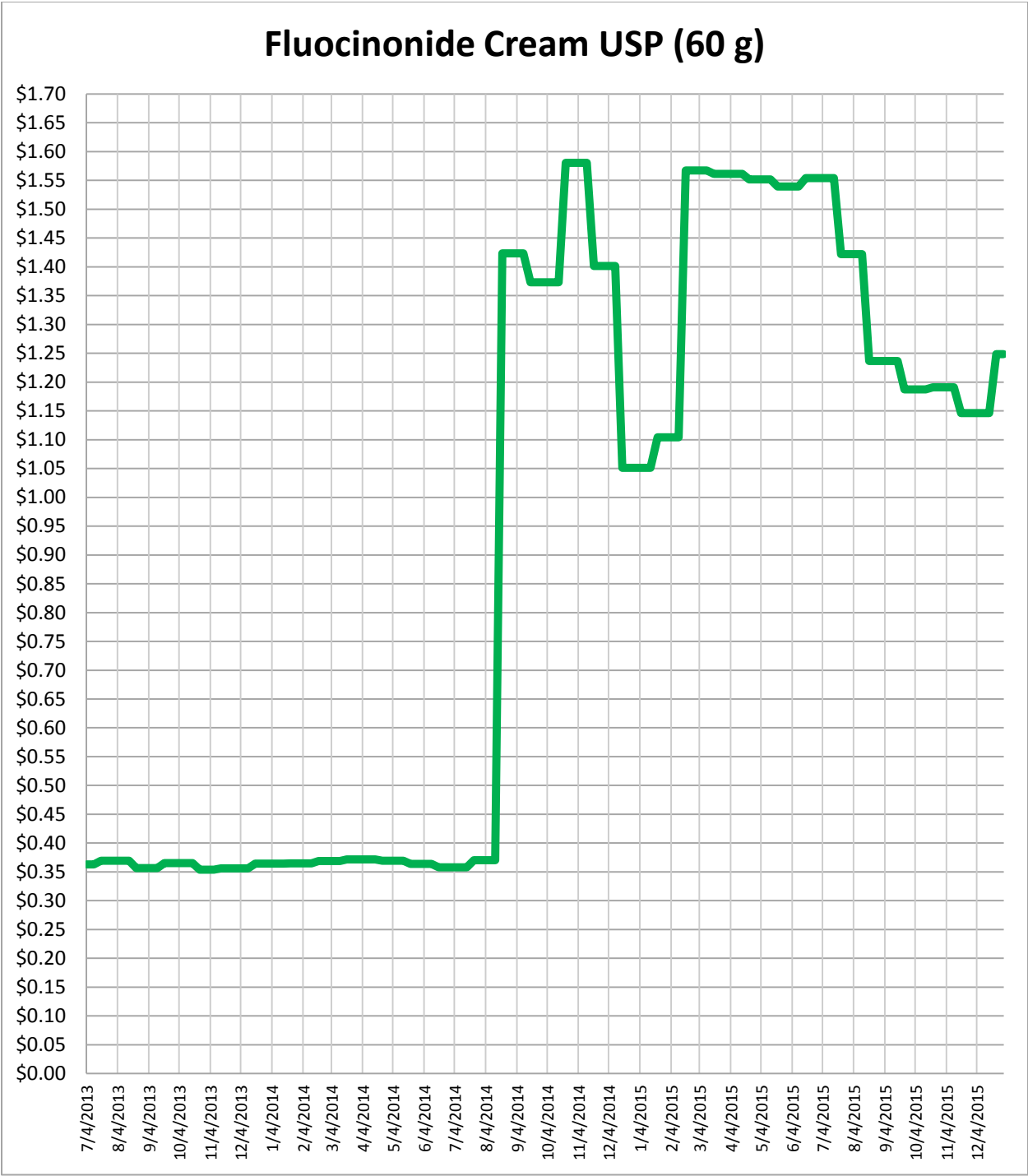
DEFENDANTS' WRONGDOING

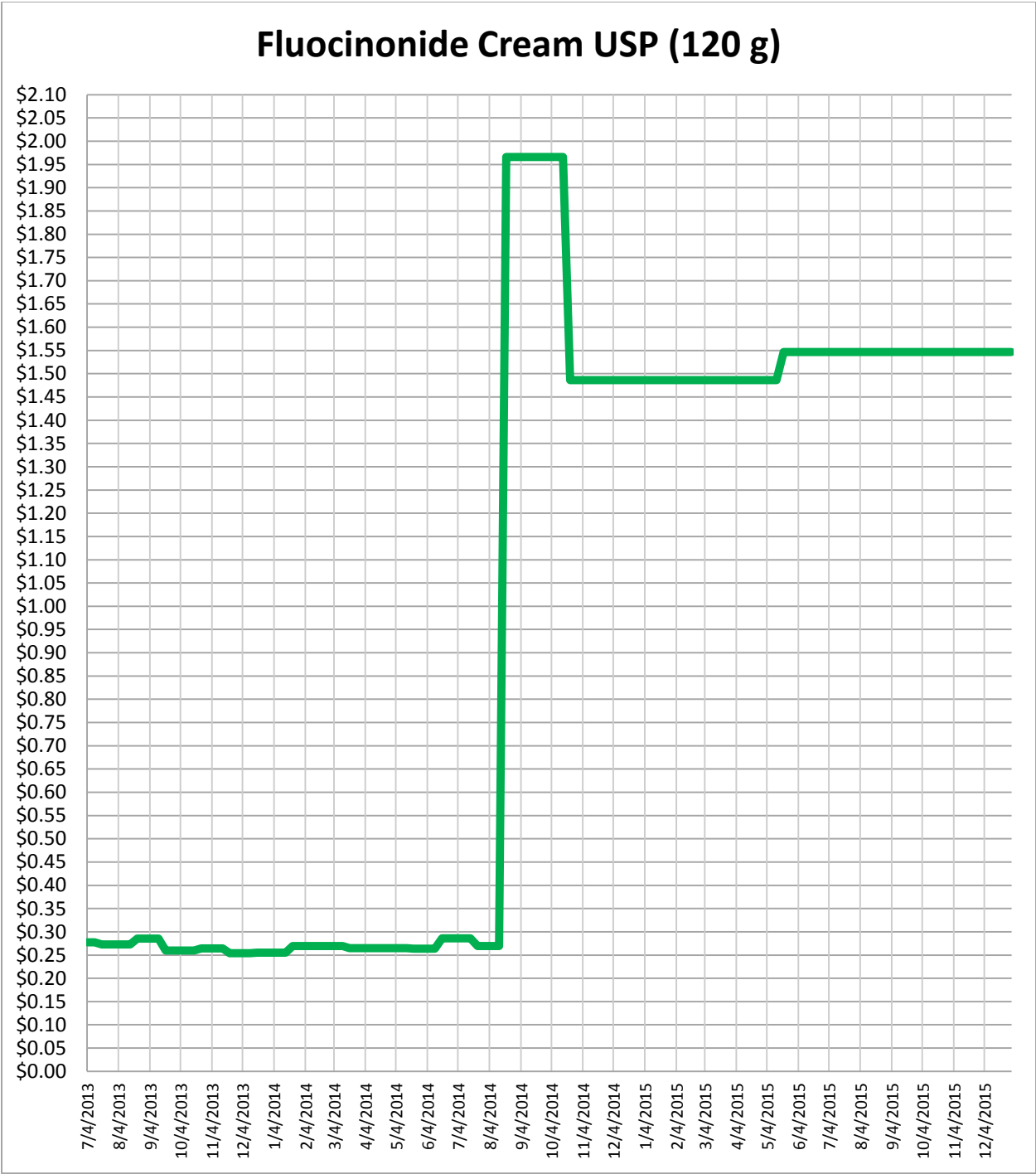
46. Trade association meetings and conferences—including those sponsored by the GPhA—as well as private dinners and meetings, provided Defendants with the means and opportunity to conspire to rig bids, fix and maintain prices for, and allocate customers of, fluocinonide. For example, representatives from Actavis, Sandoz, Taro, and Teva attended a GPhA CMC Workshop in North Bethesda, Maryland between June 3 and June 4, 2014. Within a short period after this meeting, each fluocinonide manufacturer dramatically raised its respective fluocinonide prices—in many instances, ***over 200%*** in the span of a few months.

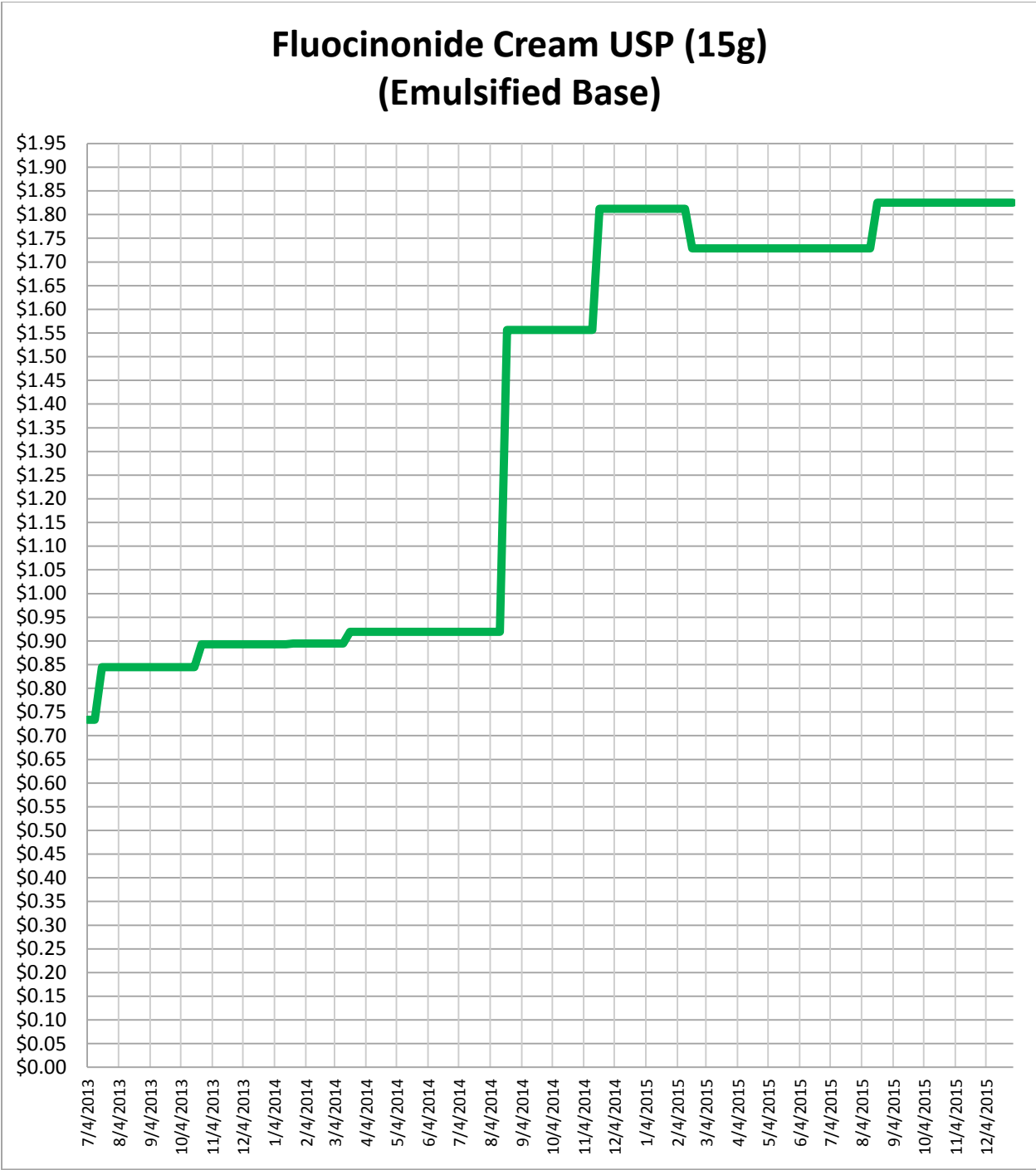
47. The Center for Medicare & Medicaid Service's National Average Drug Acquisition Cost ("NADAC") data shows that the prices for fluocinonide rose dramatically by all generic manufacturers around the same time, which together with other market conditions, is suggestive of a conspiracy to raise fluocinonide prices. The charts below show the average price per unit of generic fluocinonide topical cream (15g, 30g, 60g, 120g), cream with emulsified base (15g, 30g, 60g), gel (15g, 30g, 60g) and ointment (15g, 30g, 60g) between July 2013 and December 2015:



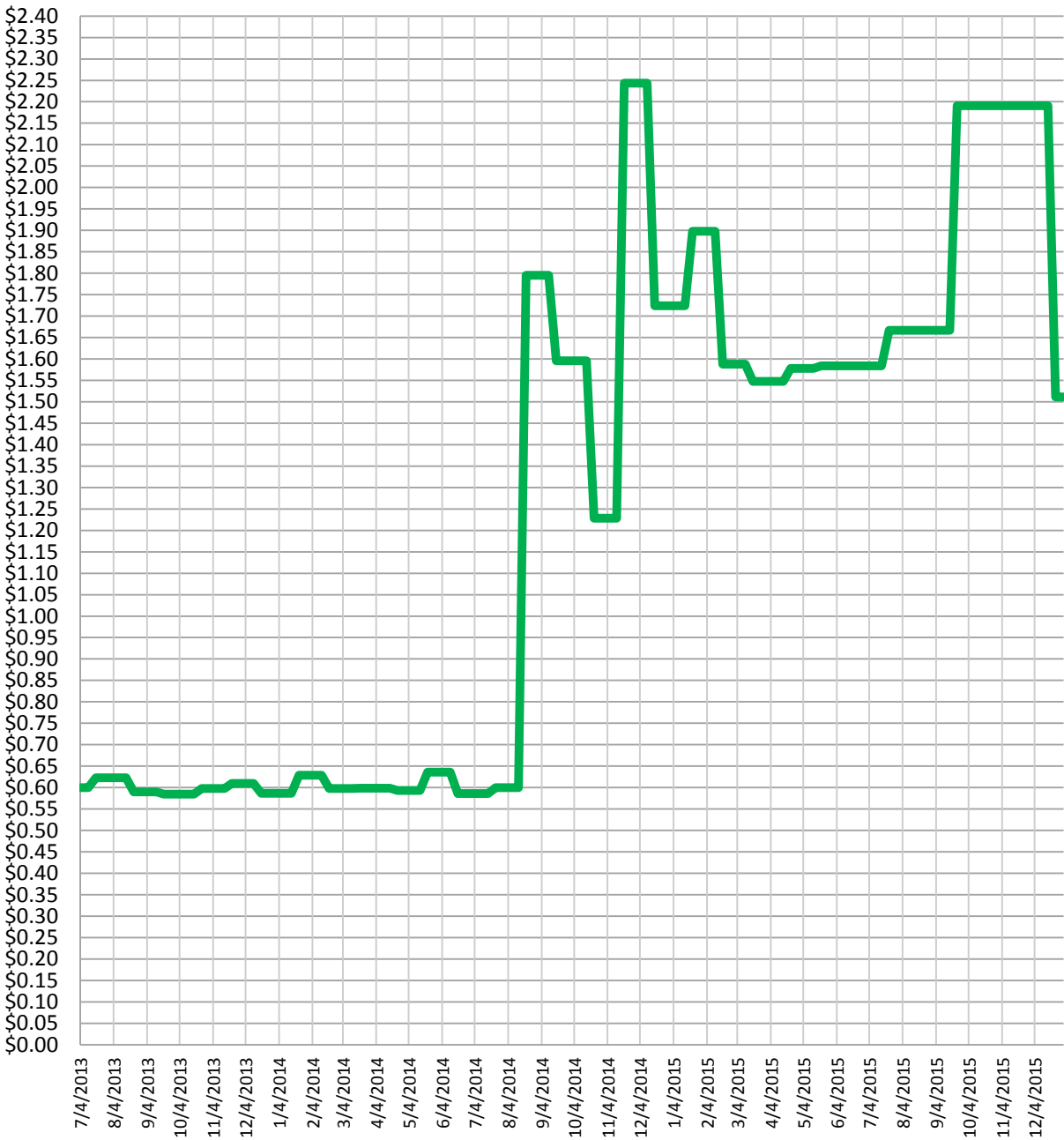


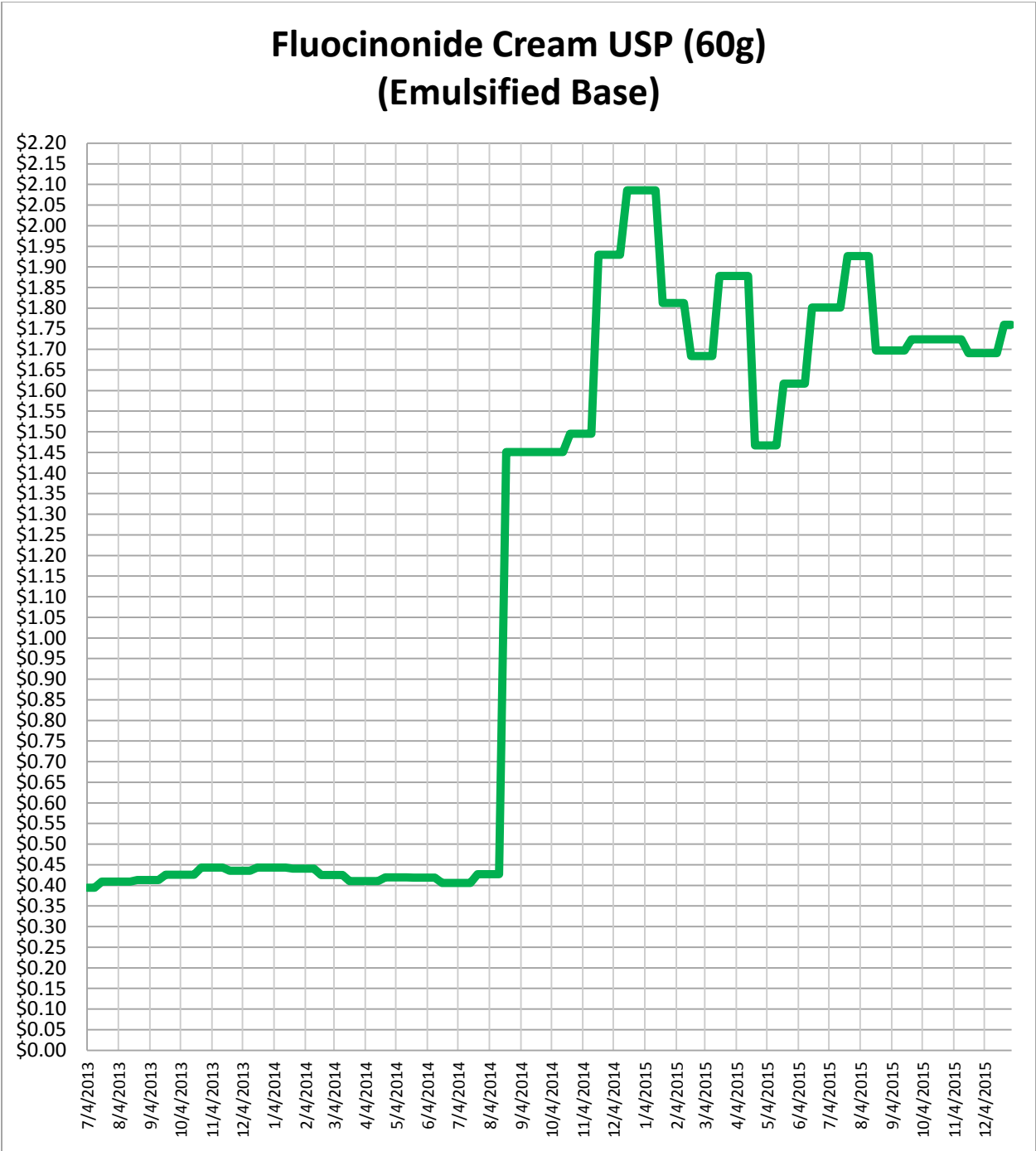


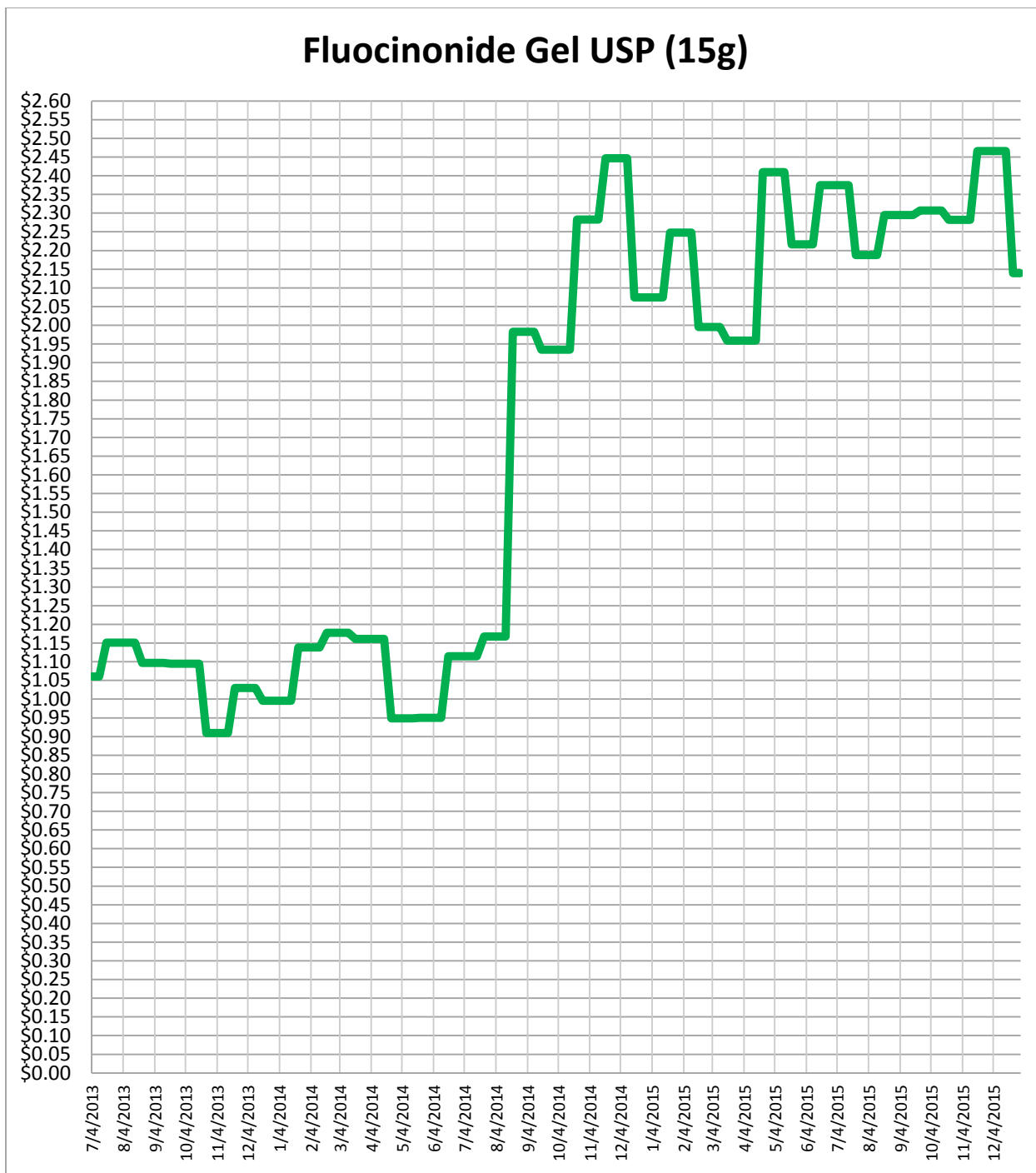


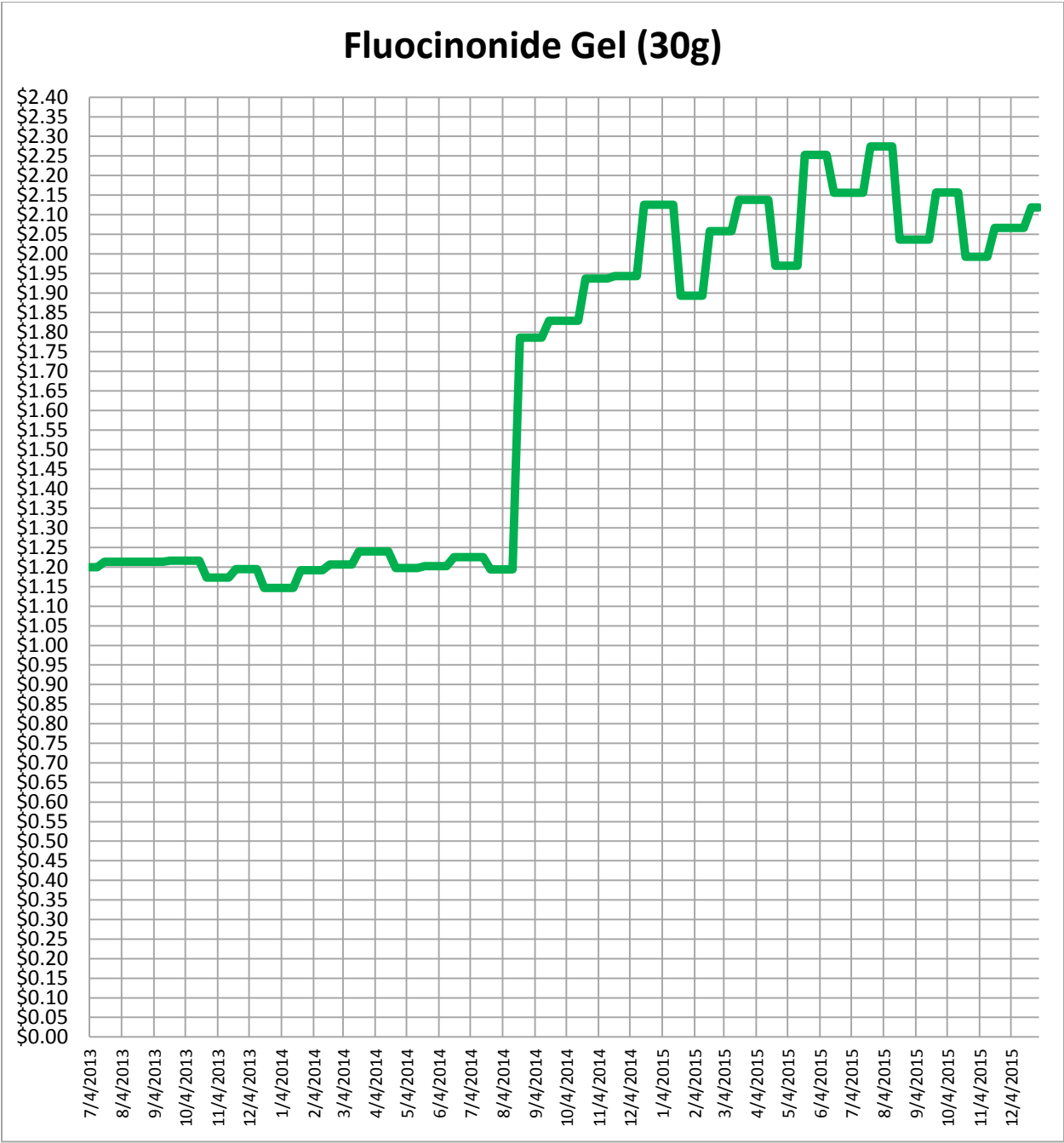


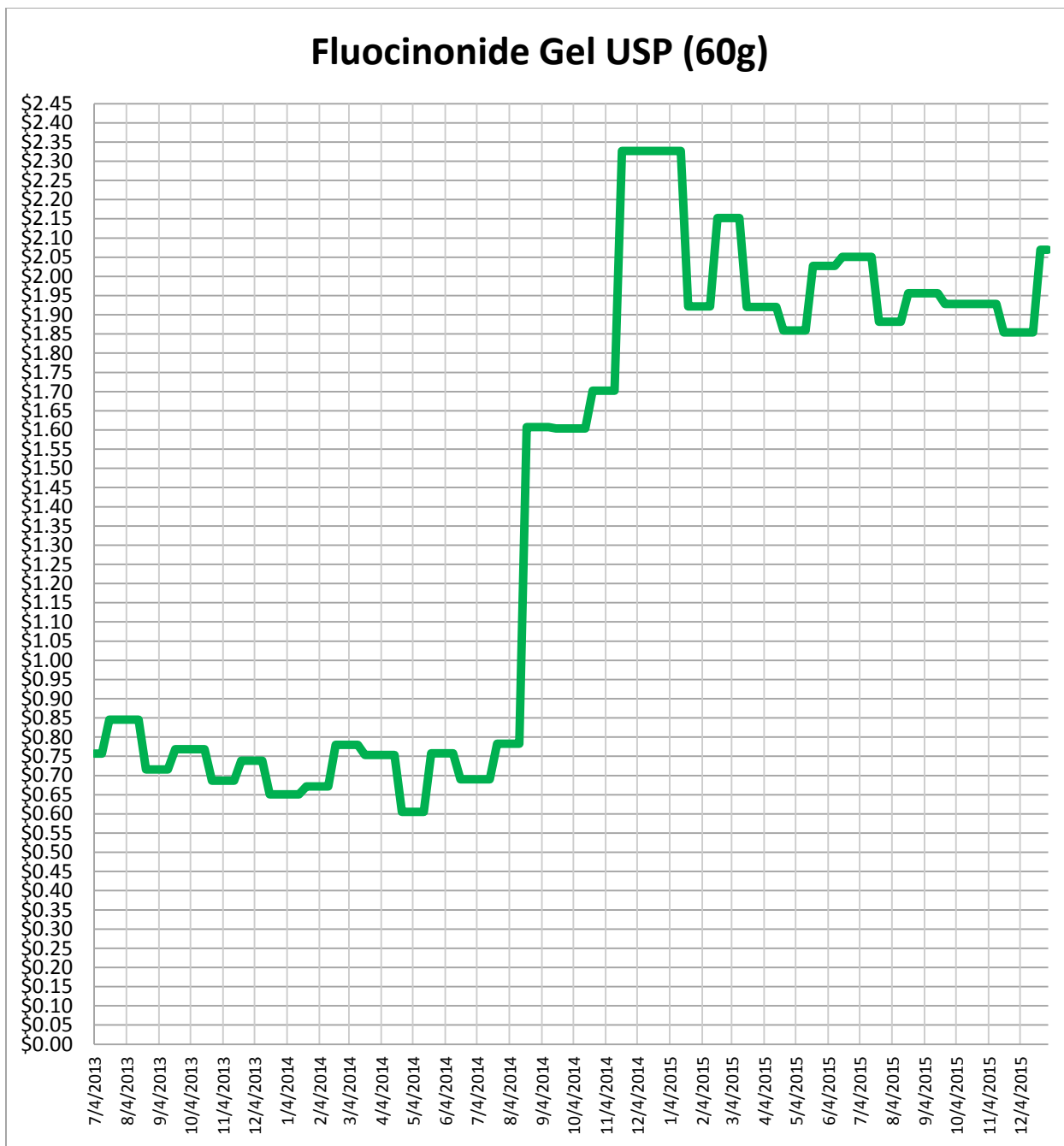
Fluocinonide Cream (Emulsified Base) (30g)

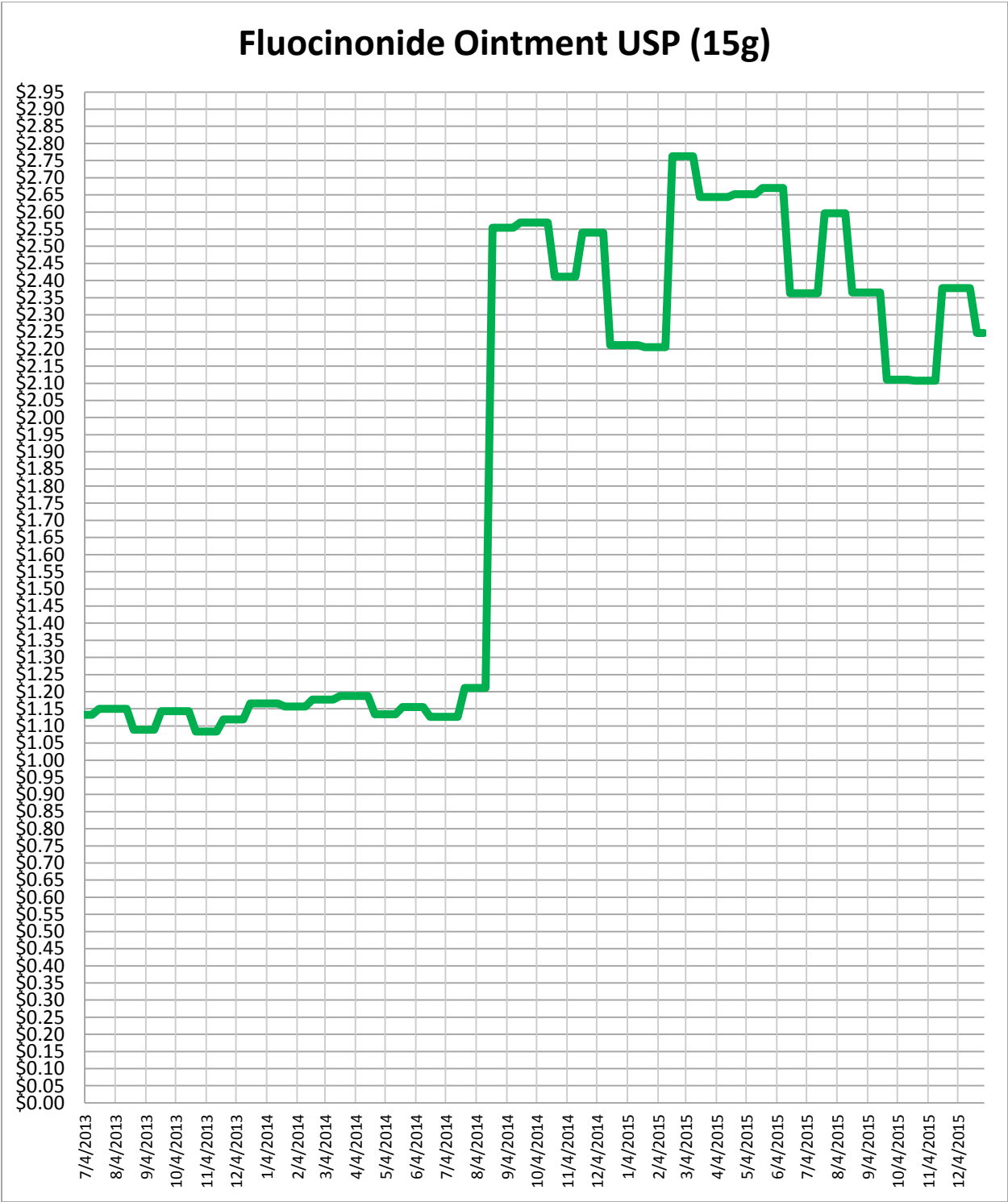


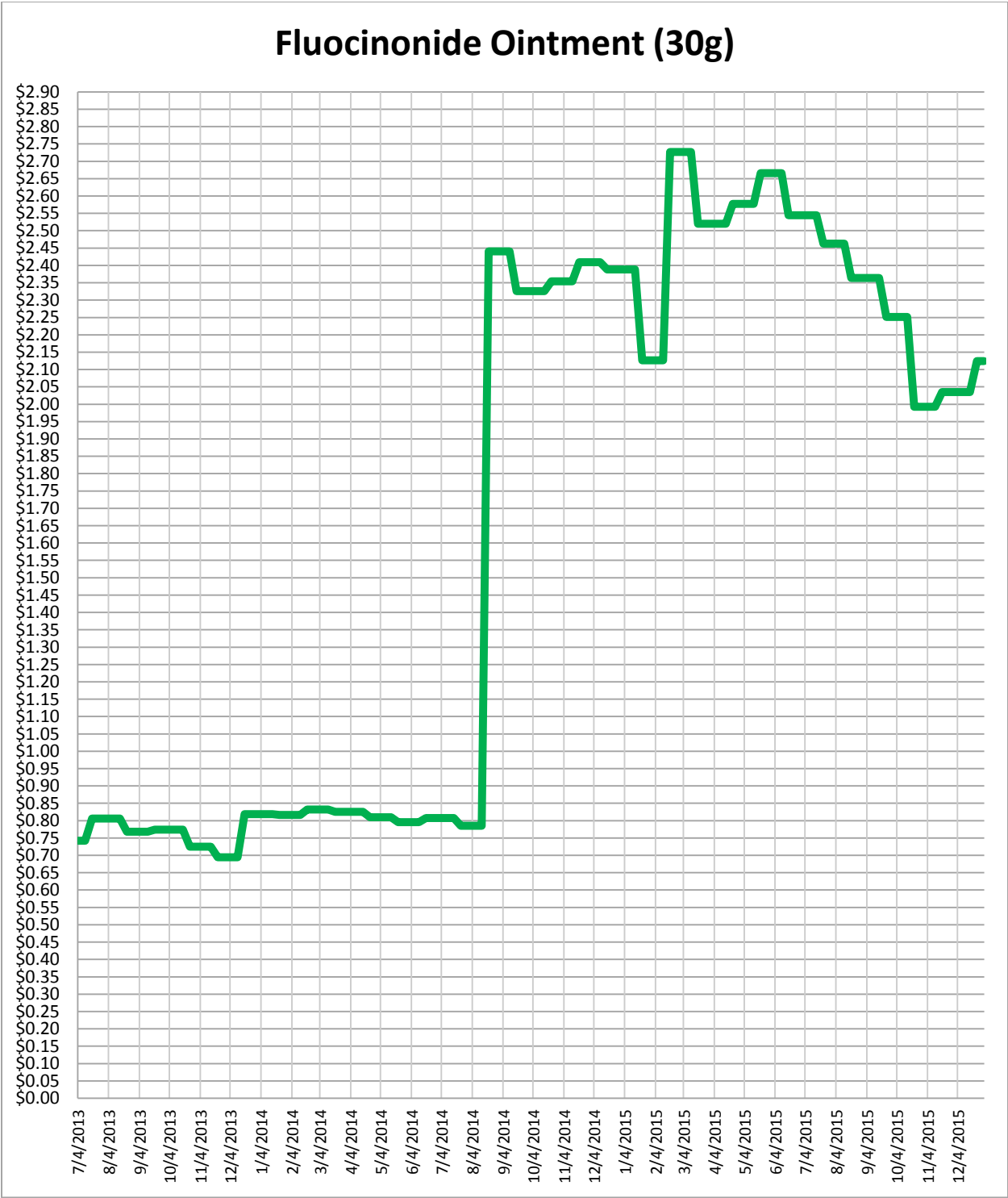


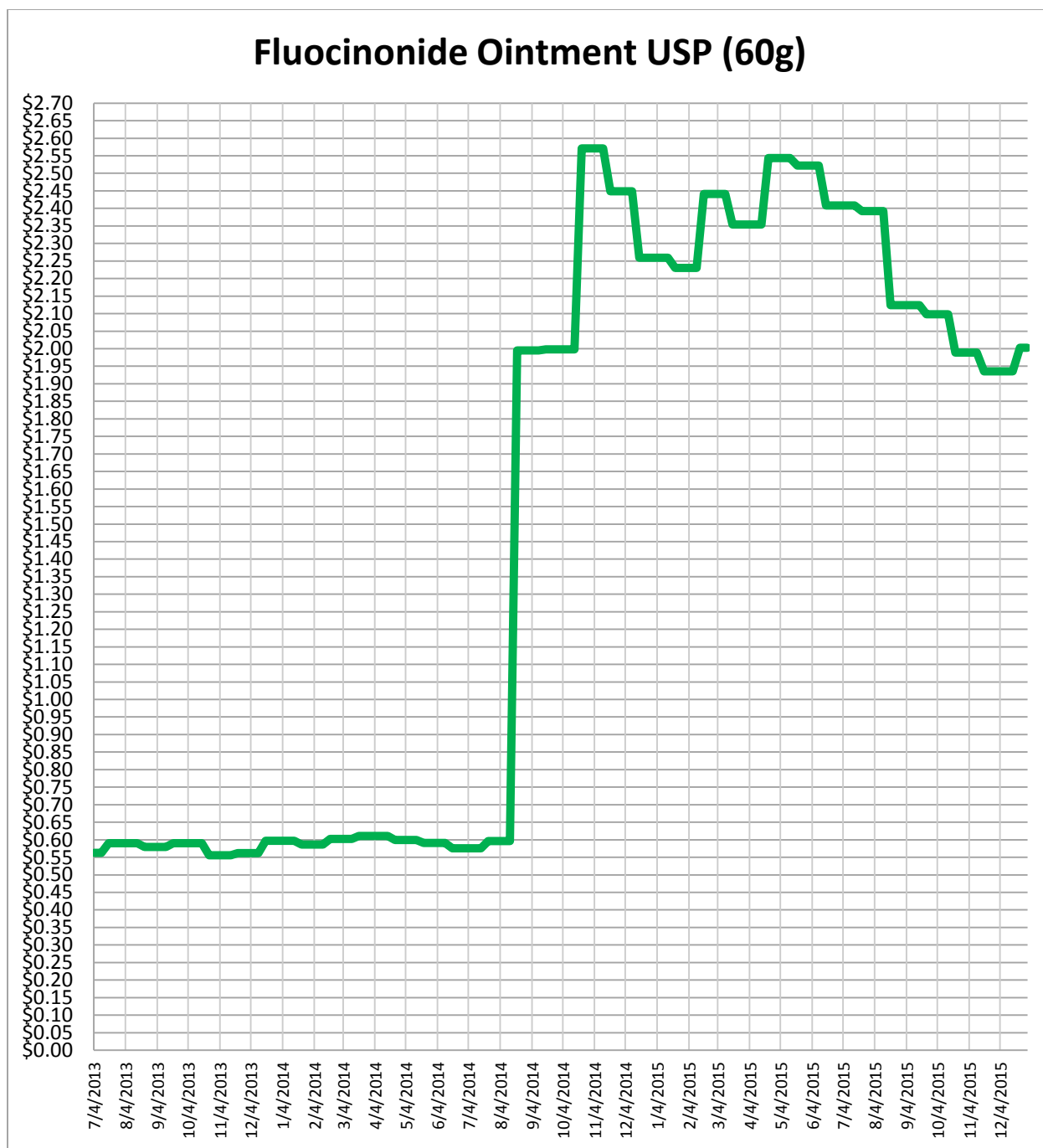












48. As seen in the charts above, between July 2013 and July 2014, fluocinonide prices were relatively stable. However, after June 2014, when Defendants attended the GPhA CMC Workshop, fluocinonide cream, cream with emulsified base, gel, and ointment prices rose dramatically, as shown in the table below.

<i>Fluocinonide Product</i>	<i>NADAC per Unit Price (July 2014)</i>	<i>NADAC per Unit Price (September 2014)</i>	<i>Percent Change in NADAC per Unit Price</i>
0.05% cream, 15g	\$0.74	\$1.65	123%
0.05% cream, 30g	\$0.52	\$1.61	209.6%
0.05% cream, 60g	\$0.37	\$1.42	283.8%
0.05% cream, 120g	\$0.27	\$1.97	629.6%
0.05% cream with emulsified base, 15g	\$0.92	\$1.56	69.6%
0.05% cream with emulsified base, 30g	\$0.60	\$1.80	200%
0.05% cream with emulsified base, 60g	\$0.43	\$1.45	237.2%
0.05% gel, 15g	\$1.17	\$1.98	67.2%
0.05% gel, 30g	\$1.19	\$1.79	50.4%
0.05% gel, 60g	\$0.78	\$1.61	106.4%
0.05% ointment, 15g	\$1.21	\$2.55	110.7%
0.05% ointment, 30g	\$0.79	\$2.44	208.9%
0.05% ointment, 60g	\$0.60	\$1.99	231.7%

49. Defendants' supracompetitive pricing for fluocinonide has been persistent through the present.

50. Further, although fluocinonide prices have eroded somewhat, they still remain substantially above the pre-August 2014 prices. Defendants' coordinated pricing has deprived, and continues to deprive, Plaintiff and members of the Classes the benefits of free and open competition—namely, lower prices for generic versions of fluocinonide. As a result, Plaintiff and members of the Classes have paid and continue to pay non-competitive prices for fluocinonide.

51. There are no market-based reasons for the pricing patterns in the fluocinonide market. Rather, Defendants sustained these supracompetitive profits by conspiring to rig bids, fix, raise, and maintain the prices of, and allocate markets and customers for, fluocinonide.

52. In formulating and effectuating their conspiracy, Defendants engaged in numerous anticompetitive activities, including, among other things:

(a) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to discuss the sale of fluocinonide in the United States;

(b) Participating, directing, authorizing, or consenting to the participation of subordinate employees in meetings, conversations, and communications with co-conspirators to allocate customers or rig bids for fluocinonide sold in the United States;

(c) Agreeing during those meetings, conversations, and communications to allocate customers for fluocinonide sold in the United States;

(d) Agreeing during those meetings, conversations, and communications not compete against each other for certain customers for fluocinonide sold in the United States;

(e) Submitting bids, withholding bids, and issuing price proposal in accordance with the agreements reached;

(f) Selling fluocinonide in the United States at collusive and noncompetitive prices; and

(g) Accepting payment for fluocinonide sold in the United States at collusive and noncompetitive prices.

53. The purpose of these secret, conspiratorial meetings, discussions, and communications was to ensure that all Defendants agreed to participate in, implement, and maintain an unlawful bid-rigging, price-fixing, and market and customer allocation scheme.

54. As a result of Defendants' unlawful agreement to restrain trade, Plaintiff and members of the Classes were injured because they paid, and continue to pay, supracompetitive prices for fluocinonide sold in the United States during the period August 1, 2014 through the present.

**THE GENERIC FLUOCINONIDE MARKET IS
SUSCEPTIBLE TO A PRICE-FIXING CONSPIRACY**

A. Factors Supporting the Existence of a Conspiracy in the Fluocinonide Market

55. The structure and other characteristics of the market for fluocinonide make it conducive to collusion and price-fixing. Specifically, during the Class Period, the fluocinonide market exhibited: (1) high barriers to entry; (2) inelasticity of demand; (3) a high degree of commoditization; (4) a high degree of concentration; (5) competitors acting against their economic self-interest; and (6) opportunities to conspire.

1. There Are High Barriers to Entry in the Market for Fluocinonide

56. A collusive arrangement that raises product prices above competitive levels would, under basic economic principles, attract new entrants seeking to benefit from the supra-competitive pricing. When, however, there are significant barriers to entry, new entrants are much less likely to enter the market. Thus, barriers to entry help facilitate the formation and maintenance of a cartel.

57. The fluocinonide market has high barriers to entry.

58. Even though fluocinonide is not protected by any patents, regulatory hurdles and the costs of doing business make market entry difficult, time consuming, and expensive. Any

generic drug manufacturer seeking to enter the fluocinonide market must file an ANDA and receive FDA approval.

59. To file an ANDA, the generic manufacturer must show that the generic product is bioequivalent to its branded counterpart and invest considerable resources in the development of production lines capable of making the drug. Historically, the cost of filing an ANDA is about \$1 million.¹¹ A generic manufacturer's production facilities must also meet CGMP standards, which increase the costs of production.

60. Moreover, a generic manufacturer that cannot produce the Active Pharmaceutical Ingredient ("API") for fluocinonide must have a reliable and affordable source of API for these products.

61. Prospective generic manufacturers must also be able to satisfy FDA regulations and guidance governing bioequivalence and bioavailability of their fluocinonide products. This requires showing that the proposed generic fluocinonide products have, among other things, the same therapeutic qualities and absorption profiles as their branded counterparts.

62. The failure to meet all FDA requirements concerning manufacturing, testing, and labeling of fluocinonide will result in the FDA delaying (or denying) approval of an ANDA. These delays can last for months or even years.

63. Even if a non-conspiring generic manufacturer were to see an opportunity to compete on price regarding fluocinonide, due to the fact that the FDA's review of ANDAs is currently significantly "backlogged," any potential entrant would necessarily be delayed for

¹¹ Testimony of Dr. Scott Gottlieb, Hearing on "Why Are Some Generic Drugs Skyrocketing in Price?" (Nov. 20, 2014), at 7.

years.¹² Indeed, the FDA has stated that as of fiscal year 2015, ANDA approvals can take 40 months or more.¹³

2. Demand for Fluocinonide Is Inelastic

64. “Elasticity” is a term used to describe the sensitivity of supply and demand to changes in one or the other. For example, demand is said to be “inelastic” if an increase in the price of a product results in only a small decline, if any, in the quantity sold of that product. In other words, customers have nowhere to turn for alternative, cheaper products of similar quality, and so continue to purchase the product despite the price increase.

65. For a cartel to profit from raising prices above competitive levels, demand must be relatively inelastic at competitive prices. Otherwise, increased prices would result in declining sales, revenues, and profits as customers purchased substitute products or declined to buy altogether. Inelastic demand is a market characteristic that facilitates collusion, allowing producers to raise their prices without triggering customer substitution and lost sales revenue.

66. Demand for fluocinonide is highly inelastic because it is a unique product for which there are no reasonable substitutes.

67. Fluocinonide is a potent topical corticosteroid (Class 2/3). It is indicated to treat a variety of skin conditions, including dermatitis and psoriasis. Even among other Class 2/3 topical corticosteroids—*e.g.*, betamethasone dipropionate, halcinonide, and desoximetasone—fluocinonide has a unique active ingredient, chemistry, and pharmacokinetics.

68. Further, even other forms of fluocinonide are not therapeutically equivalent to the fluocinonide products at issue here. For example, Medicis Pharmaceutical and Glenmark

¹² *Id.* at 7.

¹³ GAO, *Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases*, No. 16-706, at 26 (Aug. 2016), <http://www.gao.gov/assets/680/679022.pdf>.

Pharmaceuticals market fluocinonide cream 0.1%, a Class 1 corticosteroid that is more potent fluocinonide 0.05%. Because of the differences in potency between fluocinonide 0.05% and fluocinonide 0.1%, they are not therapeutically equivalent. Thus, there are no reasonable substitutes that are therapeutically equivalent.

69. Branded versions of fluocinonide do not serve as economic substitutes for generic versions of these compounds because branded products generally maintain substantial price premiums over their generic counterparts, making them inapt substitutes even when generic prices soar.

70. Thus, purchasers of fluocinonide are held captive to the supracompetitive prices that resulted from Defendants' conspiracy to fix prices and allocate markets and customers.

3. Fluocinonide Is a Commodity Product

71. When products are subject to commoditization, producers of those products are usually forced to compete on price, as opposed to other factors, such as quality and ancillary services. When price becomes a significant factor in driving demand for a product, producers of a commoditized product have an easier time colluding on price than other non-price factors because price-based collusion is much easier to implement and monitor.

72. Generic drugs of the same chemical composition are effectively commodity products because the primary mechanism through which they compete is price. Indeed, state laws require that pharmacists substitute available AB-rated generic drugs for their branded counterparts precisely because of their lower price. Defendants' fluocinonide products are AB-rated generics to their branded counterparts, enabling substitution.

73. Moreover, because generic manufacturers generally spend little effort advertising or detailing their generic compounds (*i.e.*, the practice of providing promotional materials and free samples to physicians), the primary means for one generic manufacturer to differentiate its

product from another generic competitor's product is through price reductions.¹⁴ The need to compete on price can drive producers of commodity products to conspire—as they did here—to fix prices.

4. The Generic Fluocinonide Market Is Highly Concentrated

74. A concentrated market is more susceptible to collusion and other anticompetitive practices.

75. The fluocinonide market is highly concentrated, with only a handful of companies dominating the market—Actavis, Sandoz, Taro, and Teva.

76. The limited number of fluocinonide manufacturers facilitated those manufacturers' ability to coordinate pricing of their respective products. This concentration also made it easy for them to monitor prices in the downstream market and police deviations from agreed-upon prices.

77. As the dominant players in the market for fluocinonide, Defendants were able to fix, raise, and maintain their prices on these products without competitive threats from rival generic drug manufacturers.

5. Defendants' Pricing of Fluocinonide Was Against Their Self-Interest

78. Firms in a competitive, commoditized marketplace will typically price their products aggressively, relative to their competitors' products. Firms price aggressively with the understanding that if they do not do so, other competitors will undercut their relatively high price, taking sales—and ultimately market share—away from the firms that are pricing less aggressively.

¹⁴ See Congressional Budget Office, Promotional Spending for Prescription Drugs, Economic & Budget Issues Brief (Dec. 2, 2009), at 1.

79. Here, however, rather than attempt to take sales, revenue, and market share away from one another, Defendants instead sought to meet other firms' price increases and extract supracompetitive prices from Plaintiff and members of the Classes.

80. Such conduct was against each Defendant's self-interest because rather than cut prices to gain sales, revenues, and market share, each Defendant instead sought to sacrifice these potential gains in favor of cartel pricing. Defendants' individual failures to cut prices in the face of competitors' price increases suggest that Defendants were conspiring to fix and raise prices, rather than competing on price.

6. Memberships in the Same Trade Associations Provided Defendants with Opportunities to Conspire

81. To sustain a conspiracy, the conspirators must periodically communicate to ensure that all are adhering to the collective scheme. Here, these meetings occurred primarily through (1) trade association meetings and conferences, and (2) private meetings, dinners and outings among smaller groups of generic drug manufacturers.

(a) Trade Association Meetings and Conferences

82. Defendants were members of numerous trade associations, which they used to facilitate their conspiratorial communications and implement their anticompetitive scheme to raise, maintain, and stabilize the prices of, as well as other drugs, and how to allocate markets and customers for fluocinonide, including, but not limited to, GPhA, the National Association of Chain Drug Stores ("NACDS"), Healthcare Distribution Management Association (now known as the Healthcare Distribution Alliance) ("HDMA"), and Efficient Collaborative Retail Marketing ("ECRM").

83. **GPhA:** GPhA is the largest trade association for generic and biosimilar manufacturers. Defendants Teva and Sandoz are current "Regular Members" of GPhA. In

addition, Teva's Senior Vice President of Global Affairs Debra Barrett and Sandoz's President Peter Goldschmidt serve on GPhA's Board of Directors. Defendants' representatives attended many meetings held by GPhA, including the following between 2014 and 2015:

Meeting	Meeting Date and Location	Attendees
2014 GPhA Annual Meeting	February 19-21, 2014, Orlando, Florida	Actavis, Sandoz, Taro, Teva
2014 GPhA CMC Workshop	June 3-4, 2014, Bethesda, Maryland	Actavis, Sandoz, Taro, Teva
2014 GPhA Fall Technical Conference	October 27-29, 2014, Bethesda, Maryland	Actavis, Sandoz, Taro, Teva
2015 GPhA Annual Meeting	February 9-11, 2015, Miami Beach, Florida	Actavis, Sandoz, Taro, Teva
2015 GPhA CMC Workshop	June 9-10, 2015, Bethesda, Maryland	Actavis, Sandoz, Taro, Teva
2015 GPhA Fall Technical Conference	November 2-4, 2015, Bethesda, Maryland	Actavis, Sandoz, Taro, Teva

84. **NACDS:** NACDS is a national trade association representing chain community pharmacies. Its members include drug manufacturers, wholesalers, and retail chain pharmacies. Defendants Sandoz, Taro, and Teva are members of NACDS. NACDS holds regular industry events, including annual and regional conferences, that Defendants and other generic manufacturers attended.

85. **HDMA:** HDMA is a national trade association that represents "primary pharmaceutical distributors" which links the nation's drug manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, and clinics.¹⁵ HDMA holds regular conferences where its members, which include generic drug manufacturers, meet to discuss various issues

¹⁵ <https://www.healthcaredistribution.org/about>.

affecting the pharmaceutical industry. For example, Actavis, Teva, and Taro attended HDMA's 2015 Distribution Management Conference.¹⁶

86. Although HDMA's membership lists are not publicly available, upon information and belief, HDMA members include some or all Defendants, as well as certain of their employees. For example, Teva's Senior Director of Sales and Trade Relations Teri Coward serves as a member of HDMA's Industry Relations, a position she has held since 2010.¹⁷

87. **ECRM:** ECRM is a broad-based trade association that includes not only stakeholders from the medical and pharmaceutical industry, but other industries as well. ECRM's primary mission is "to strengthen the business practices of our clients by offering Efficient Program Planning Sessions (EPPS) that are supported by innovative technology solutions."¹⁸ Within ECRM, however, there are discrete program and conferences dedicated solely to distribution and sales of generic pharmaceutical products. For example, each year, ECRM holds a "Retail Pharmacy Generic Pharmaceuticals Efficient Program Planning Session." Attendees have included representatives from Defendants Actavis, Sandoz, Taro, and Teva.¹⁹

88. As uncovered in the state attorneys' general investigation, at these various conferences and trade shows, representatives from Defendants, as well as other generic drug manufacturers, discussed their respective businesses and customers. These discussions would occur at social events, including lunches, cocktail parties, dinners, and golf outings, that usually accompanied these conferences and trade shows. Defendants' employees used these

¹⁶ <https://www.healthcaredistribution.org/events/2015-distribution-management-conference/previous-attendees>.

¹⁷ <https://www.healthcaredistribution.org/persons/teri-coward>.

¹⁸ <https://ecrm.marketgate.com/AboutECRM/>.

¹⁹ <https://ecrm.marketgate.com/Events/Attendees.aspx?s=3610&rt=S>.

opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers.

(b) Private Meetings, Dinners, and Outings

89. In addition to trade association meetings and events, Defendants, and other generic manufacturers often participated in smaller group dinners and other private meetings. A large number of generic drug manufacturers, including Defendants Actavis, Sandoz Taro, and Teva, are headquartered in close proximity to one another in New Jersey or eastern Pennsylvania, giving them easier and more frequent opportunities to meet and collude.

90. As uncovered by the state attorneys' general investigation, high-level executives of many generic drug manufacturers get together periodically for what at least some of them refer to as "industry dinners." For example, in January 2014, at a time when the prices of a number of generic drugs were reportedly soaring, at least thirteen high-ranking male executives, including CEOs, Presidents, and Senior Vice Presidents of various generic drug manufacturers, met at a steakhouse in Bridgewater, New Jersey.

91. Female generic pharmaceutical sales representatives also get together regularly for what they refer to as a "Girls' Night Out" ("GNO"), or alternatively "Women in the Industry" meetings and dinners. During these GNOs, meetings and dinners, these representatives meet with their competitors and discuss competitively sensitive information. One such GNO held in May 2015 in Baltimore, Maryland, was attended by representatives of Defendant Teva, among others.

GOVERNMENT INVESTIGATIONS INTO GENERIC DRUG PRICING

A. Congressional Investigations into Generic Drug Pricing

92. As news reports have proliferated with respect to the dramatic rise in price of certain generic drugs, members of Congress have expressed a growing concern as to what is driving these price hikes. On October 2, 2014, Representative Elijah E. Cummings, the Ranking

Member of the House Committee on Oversight and Government Reform, and Senator Bernard Sanders, Chairman of the Subcommittee on Primary Health and Aging, Senate Committee on Health, Education, Labor and Pensions, “sent letters to 14 drug manufacturers requesting information about the escalating prices of generic drugs used to treat everything from common medical conditions to life-threatening illnesses.”²⁰

93. These letters were delivered to the heads of Actavis, Apotex, Dr. Reddy’s, Impax, Mylan, Par Pharmaceutical, Teva, Zydus, Endo, Heritage Pharmaceuticals, and Marathon Pharmaceuticals, seeking information about the pricing of divalproex ER, pravastatin, digoxin, doxycycline, albuterol sulfate, glycopyrrolate, neostigmine methylsulfate, benazepril/hydrochlorothiazide, Isuprel® (isoproterenol hydrochloride), and Nitropress® (nitroprusside).

94. Each letter stated:

This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community of Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country “have seen huge upswings in generic drug prices that are hurting patients['] and pharmacies['] ability to operate” and “77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug’s acquisition price.” These price increases have a direct impact on patients’ ability to purchase their needed medications. The NCPA survey found that “pharmacists reported patients declining their medication due to increased co-pays,” and “84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a ‘very significant’ impact on their ability to remain in business to continue serving patients.”²¹

95. In addition to sending letters to the generic drug manufacturers listed above, Senator Sanders and Representative Cummings wrote a joint letter to Sylvia Burwell, the

²⁰ Ranking Members Cummings and Chairman Sanders Investigate Staggering Price Increases for Generic Drugs, <http://www.sanders.senate.gov/download/face-sheet-on-generic-drug-price-increases?inline=file>.

²¹ See, e.g., Ltr. from Sen. Bernard Sanders & Rep. Elijah E. Cummings to Arthur P. Bedrosian (Oct. 2, 2014), <http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file> (citing Letter from B. Douglas Hoey to Sen. Tom Harkin, et al. (Jan. 8, 2014), <https://www.ncpanet.org/pdf/leg/jan14/letter-generic-spikes.pdf>)).

Department of Health and Human Services Secretary, stating, “The federal government must act immediately and aggressively to address the increasing costs of these drugs.”²²

96. The Senate Subcommittee on Primary Health and Aging held a hearing on November 20, 2014. Although the Presidents and CEOs of Lannett, Teva, and Marathon Pharmaceuticals were scheduled to attend the hearing, none appeared. Many panelists agreed that reduced competition across various generic drugs has contributed to the price hikes observed in the overall market.

97. Subsequent congressional hearings concerning the dramatic rise of generic drug prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging’s December 9, 2015 hearing, Erin D. Fox, PharmD Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating, “When medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage.”²³

98. On February 24, 2015, Senator Sanders and Representative Cummings wrote to Daniel R. Levinson, the Inspector General of the Department of Health and Human Services, imploring the department to “examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare

²² Congressional Panel to Probe Generic Drug Price Hikes (Nov. 11, 2014), <http://www.sanders.senate.gov/newsroom/press-releases/congressional-panel-to-probe-generic-drug-price-hikes>.

²³ Statement of Erin R. Fox, PharmD Director, Drug Information Service, Hearing on “Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines” (Dec. 9, 2015), at 7, http://www.aging.senate.gov/imo/media/doc/SCA_Fox_12_9_15.pdf.

and Medicaid programs.”²⁴ On April 13, 2015, Inspector General Levinson responded to Senator Sanders and Representative Cummings’s letter, stating that his office planned “to update our previous review of generic drug price increases under the Medicaid drug rebate program.”²⁵

B. Federal and State Antitrust Investigations into Generic Drug Pricing

99. Generic pricing patterns have also captured the attention of federal and state enforcement authorities in the United States. Generic drug manufacturers, including Defendant Taro, have received subpoenas or requests for information concerning their pricing of generic drugs, as well as their communications with their competitors for those drugs.

100. Recent news reports have confirmed the sweeping nature of the DOJ’s investigation: at least two-dozen drugs and a dozen drug companies are under criminal investigation.

101. A federal grand jury investigating the matter is empaneled in the Eastern District of Pennsylvania. The result of these investigations could result in the imposition of substantial fines and criminal pleas for generic manufacturers, and jail time for company executives. Some analysts have estimated that the DOJ could impose fines in excess of \$1 billion.²⁶

102. To date, the following generic drug companies have been contacted in connection with both federal and state antitrust probes:

103. *Actavis*. Defendant Actavis’s parent Allergan plc also disclosed in public filings that they received subpoenas from DOJ. Allergan reported that, on June 25, 2015, Actavis

²⁴ Letter from Hon. Bernard Sanders and Elijah Cummings to Hon. Daniel Levinson (Feb. 24, 2015), <http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file>.

²⁵ Letter from Hon. Daniel Levinson to Hon. Bernard Sanders (Apr. 13, 2015), <http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file>.

²⁶ Eric Saonowsky, *DOJ’s price-fixing investigation could lead to sizable liabilities, analyst says*, FiercePharma (Nov. 10, 2016), <http://www.fiercepharma.com/pharma/doj-s-price-fixing-investigation-could-lead-to-sizable-liabilities-analyst-says>.

received a subpoena from DOJ “seeking information relating to the marketing and pricing of certain of the Company’s generic products and communications with competitors about such products.”²⁷

104. **Teva.** On August 4, 2016, Defendant Teva disclosed that “[o]n June 21, 2015, Teva USA received a subpoena from the Antitrust Division of the United States Department of Justice seeking documents and other information relating to the marketing and pricing of certain of Teva USA’s generic products and communications with competitors about such products.”²⁸ In that same filing, Teva disclosed that on July 12, 2016, “Teva USA received a subpoena from the Connecticut Attorney General seeking documents and other information relating to potential state antitrust law violations.”²⁹

105. **Taro.** On September 9, 2016, Defendant Taro disclosed that on September 8, 2016, it and two senior officers in Taro’s commercial team, “received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products, and certain other related matters.”³⁰

106. **Lannett.** In July 2014, Lannett revealed in SEC filings that they had received subpoenas from the CTAG in connection with its investigation into whether “anyone engaged in a contract, combination or conspiracy in restraint of trade or commerce which has the effect of

²⁷ Allergan, SEC 2015 Form 10-K, at F-106.

²⁸ Teva, SEC Form 6-K at 25 (Aug. 4, 2016), <http://ir.tevapharm.com/phoenix.zhtml?c=73925&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTExMDcyODU1JkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVEIPTI9FTIRJUKUmc3Vic2lkPTU3>.

²⁹ *Id.*

³⁰ Taro, SEC Form 6-K (Sept. 9, 2016), <http://phx.corporate-ir.net/phoenix.zhtml?c=114698&p=irol-SECText&TEXT=aHR0cDovL2FwaS50ZW5rd2l6YXJkLmNvbS9maWxpbmcueG1sP2lwYWdlPTExMTM0MjUwJkRTRVE9MCZTRVE9MCZTUURFU0M9U0VDVEIPTI9FTIRJUKUmc3Vic2lkPTU3>.

(i) fixing, maintaining or controlling prices of digoxin or (ii) allocating and dividing customers or territories relating to the sale of digoxin in violation of Connecticut antitrust law.”³¹

107. The information and documents sought by the CTAG included: (1) the identification of “all persons at Lannett with any supervisory, executive or other significant non-ministerial responsibility related to the pricing or sale of Digoxin”; (2) the identification and production of “all documents or communications referring or relating to any decision(s), by you or any other company, to increase the price of Digoxin”; (3) the production of “[a]ll marketing plans, strategic plans or any other documents relating to the development, manufacture and commercialization of Digoxin”; and (4) the identification and production of “written compliance policy directed to the antitrust laws.”

108. Five months later, on November 10, 2014, Lannett disclosed in an SEC filing that a senior sales and marketing executive was served with a DOJ grand jury subpoena “relating to a federal investigation of the generic industry into possible violations of anti-trust laws.”³²

109. On December 5, 2014, Lannett disclosed in a Form 8-K that it received another “grand jury subpoena related to the continuing federal investigation of the generic pharmaceutical industry into possible violations of the Sherman Act.”³³ Lannett further disclosed that the “subpoena requests corporate documents from the Company relating to corporate, financial, and employee information, communications or correspondence with competitors

³¹ Impax Laboratories (IPXL) Receives Subpoena from Connecticut AG, [http://www.streetinsider.com/Corporate+News/Impax+Laboratories+\(IPXL\)+Receives+Subpoena+from+Connecticut+AG/9662945.html](http://www.streetinsider.com/Corporate+News/Impax+Laboratories+(IPXL)+Receives+Subpoena+from+Connecticut+AG/9662945.html); Lannett Receive Inquiry from Connecticut Attorney General, <http://finance.yahoo.com/news/lannett-receives-inquiry-connecticut-attorney-153300612.html>.

³² Ed Silverman, *Justice Department Probes Generic Companies After Price Hike Reports*, Wall. St. J. (Nov. 10, 2014).

³³ Lannett Form 8-K (Dec. 5, 2014), http://www.sec.gov/Archives/edgar/data/57725/000110465914085406/a14-25827_18k.htm.

regarding the sale of generic prescription medications, and the marketing, sale, or pricing of certain products.”³⁴ In a 2015 SEC filing, Lannett further disclosed that the federal subpoenas requested information and documents for the period 2005 through the dates the subpoenas were issued.

110. **Impax.** In July 2014, Impax disclosed in received a subpoena from the CTAG concerning Impax’s sales of generic digoxin and whether it agreed with others to fix prices or allocate customers or territories. In November 2014, Impax disclosed that it also received a federal grand jury subpoena requesting testimony and documents about “any communication or correspondence with any competitor about the sale of generic drugs.”³⁵ The scope of the subpoenas was not limited to a particular drug or a particular timeframe.

111. Later, Impax further disclosed that on March 13, 2015, “the Company received a grand jury subpoena from the Justice Department requesting the production of information and documents regarding the sales, marketing, and pricing of certain generic prescription medications. In particular the Justice Department’s investigation currently focuses on four generic medications: digoxin, terbutaline sulfate tablets, prilocaine/lidocaine cream, and calcipotriene topical solution.”³⁶

112. **Par.** The federal grand jury’s probe continues to expand. In an SEC Form 10-K for 2014, Par disclosed that it had received a subpoena from DOJ “requesting documents related to communications with competitors regarding our authorized generic version of Covis’s

³⁴ *Id.*

³⁵ Impax SEC Form 8-K (Nov. 6, 2014), <https://www.sec.gov/Archives/edgar/data/1003642/000119312514402210/d816555d8k.htm>.

³⁶ Impax, SEC 2015 Form 10-K, at F-53.

Lanoxin® (digoxin) oral tablets and our generic doxycycline products.”³⁷ Moreover, in that same filing Par revealed that the CTAG served a subpoena on Par on August 6, 2014 “requesting documents related to our agreement with Covis Pharma S.a.r.l. to distribute an authorized generic version of Covis’s Lanoxin® (digoxin) oral tablets.”³⁸ Par stated that it completed its response on October 28, 2014.

113. **Mylan.** Mylan similarly disclosed in a 2016 SEC filing that it received a subpoena from DOJ “seeking information relating to the marketing, pricing, and sale of our generic Doxycycline products and any communications with competitors about such products.”³⁹ Mylan received a similar subpoena from the CTAG, seeking “information relating to the marketing, pricing and sale of certain of the Company’s generic products (including Doxycycline) and communications with competitors about such products.”⁴⁰

114. More recently, on November 10, 2016, Mylan disclosed that DOJ issued a subpoena to Mylan and certain employees and senior management “seeking additional information relating to the marketing, pricing and sale of our generic Cidofovir, Glipizide-metformin, Propranolol and Verapamil products and any communications with competitors about such products.”⁴¹ Significantly, Mylan disclosed that “[r]elated search warrants also were executed” in connection with DOJ’s investigation.⁴²

³⁷ Par Pharmaceuticals Companies, Inc., SEC 2014 Form 10-K, at 37.

³⁸ *Id.*

³⁹ Mylan, SEC 2015 Form 10-K, at 160.

⁴⁰ *Id.*

⁴¹ Mylan SEC Form 10-Q, at 58 (Nov. 10, 2016), http://apps.shareholder.com/sec/viewerContent.aspx?companyid=ABEA-2LQZGT&docid=11678486#MYL10Q_20160930XDOC_HTM_S582E80BDD4215D11A4040D12D4C2E297.

⁴² *Id.*

115. **Sun.** On or about May 28, 2016, Sun disclosed that it had received a subpoena from DOJ “seeking information about the pricing and marketing of the generic drugs it sells in the United States.”⁴³ DOJ also sought documents related to “employee and corporate records and communications with competitors.”⁴⁴

116. **Dr. Reddy’s.** On or about August 11, 2016, Dr. Reddy’s disclosed in an SEC filing that it had received a subpoena from the DOJ on July 6, 2016, “seeking information relating to the marketing, pricing and sale of certain . . . generic products and any communications with competitors about such products.”⁴⁵ In that same filing, Dr. Reddy’s disclosed that it had received a subpoena from the CTAG concerning the same matters.

117. **Mayne Pharma.** In its 2016 Annual Report, Mayne Pharma Ltd. disclosed that it was “one of numerous generic pharmaceutical companies to receive a subpoena from the Antitrust Division of the US Department of Justice [] in the last two years seeking information relating to marketing, pricing and sales of select generic drugs.”⁴⁶ In the same Annual Report, Mayne Pharma also disclosed that it had received a subpoena from the CTAG seeking similar information.

118. **Zydus.** Although Zydus is not publicly traded in the United States and thus not subject to reporting requirements under federal securities laws, recent press reports have stated

⁴³ India’s Sun Pharma Gets U.S. Subpoena Over Generic Drugs Pricing, Fortune (May 28, 2016), <http://fortune.com/2016/05/28/sun-pharma-drug-price-subpoena>.

⁴⁴ *Id.*

⁴⁵ Dr. Reddy’s, SEC Form 6-K (Aug. 31, 2016).

⁴⁶ Mayne Pharma, 2016 Annual Report, at 75.

the Zydus is also a target of the DOJ's sweeping investigation.⁴⁷ According to one article, Zydus is being investigated in connection with its marketing and sale of divalproex ER.⁴⁸

C. DOJ and State Attorneys General File Their First Complaints Alleging that Generic Drug Manufacturers Conspired to Fix Prices, Rig Bids, and Allocate Customers and Markets

119. On December 13, 2016, DOJ filed their first charges in connection with their two-year investigation into collusion in the generic pharmaceuticals industry. DOJ charged former Heritage Pharmaceutical executives Jeffrey Glazer and Jason Malek each with two felony counts under the Sherman Act, for conspiring with others to fix prices, rig bids, and allocated customers for the generic drugs doxycycline and glyburide. According to reports, Messrs. Glazer and Malek are expected to plead guilty and are cooperating with DOJ's continued investigation.⁴⁹

120. The next day, on December 14, 2016, 20 state attorneys general sued generic drug manufacturers Aurobindo Pharma, Citron Pharma, Heritage Pharmaceuticals, Mayne Pharma, Mylan, and Teva for their scheme to rig bids and fix and maintain prices, and allocate customers, for doxycycline and glyburide. According to their complaint, the state attorneys general have uncovered collusive conduct involving "numerous different drugs and competitors, which will be acted upon at the appropriate time."⁵⁰

ANTITRUST IMPACT

121. During the relevant period, Plaintiff and members of the Classes purchased substantial amounts of fluocinonide indirectly from Defendants. As a result of Defendants'

⁴⁷ Rupali Mukherjeel, *US polls, pricing pressure may hit Indian pharma cos*, The Times of India, <http://timesofindia.indiatimes.com/business/india-business/US-polls-pricing-pressure-may-hit-Indian-pharma-cos/articleshow/55301060.cms>.

⁴⁸ *Hillary win may pose pricing challenges for pharma cos: Report*, F. World (Nov. 7, 2016), <http://www.firstpost.com/world/hillary-win-may-pose-pricing-challenges-for-pharma-cos-report-3093544.html>.

⁴⁹ Tom Schoenberg, David McLaughlin, and Sophia Pearson, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, Bloomberg (Dec. 14, 2016), <http://bloom.bg/2hNRrpb>.

⁵⁰ Compl. at ¶ 9, *Connecticut v. Aurobindo Pharma USA, Inc.*, 16-cv-02056 (D. Conn.)

illegal conduct, these purchasers have paid, and continue to pay, artificially inflated prices for fluocinonide. The prices paid were substantially higher than the prices that Plaintiff and members of the Classes would have paid absent the illegal conduct alleged in this Complaint.

122. As a consequence, purchasers of fluocinonide have sustained substantial losses and damage to their business and property in the form of overcharges—and their losses continue to date. The full amounts, forms, and components of such damages will be calculated after discovery and upon proof at trial.

123. Defendants’ efforts to restrain competition in the market for fluocinonide have substantially affected intrastate and interstate commerce—and continue to do so.

124. At all material times, Defendants manufactured, promoted, distributed, and sold substantial amounts of fluocinonide in a continuous and uninterrupted flow of commerce throughout the United States. Defendants’ anticompetitive conduct had substantial intrastate effects in every state of purchase because, among other things, consumers and third-party payors within each state were forced to pay supracompetitive prices for fluocinonide.

125. At all times, Defendants transmitted funds and contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state lines in connection with the sale of fluocinonide.

126. Economists recognize that any overcharge at a higher level of distribution generally results in higher prices at every level below. Professor Herbert Hovenkamp explains that “[e]very person at every stage in the chain will be poorer” as a result of the anticompetitive

price at the top.⁵¹ He also says that “[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level.”⁵²

127. The institutional structure of pricing and regulation in the pharmaceutical drug industry ensures that overcharges at the higher level of distribution are passed on to end-payors. Wholesalers and retailers passed on the inflated prices of fluocinonide to Plaintiff and members of the Classes.

128. Defendants’ anticompetitive conduct enabled Defendants to charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent Defendants’ unlawful actions.

129. The prices were inflated as a direct and foreseeable result of Defendants’ anticompetitive conduct.

130. The inflated prices that Plaintiff and members of the Classes have paid for fluocinonide, and continue to pay, are traceable to and the foreseeable result of, the overcharges by Defendants.

CLASS ALLEGATIONS

131. Plaintiff brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(2), on behalf of itself and a nationwide class of similarly situated individuals seeking injunctive and equitable relief:

The Injunctive Class:

All persons or entities in the United States and its territories who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for fluocinonide, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or

⁵¹ See Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice*, at 564 (1994).

⁵² *Id.*

beneficiaries, from at least as early as August 1, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased.

132. Plaintiff also brings this action as a class action, under Fed. R. Civ. P. 23(a) and (b)(3), on behalf of itself and a class of similarly situated individuals seeking damages arising from Defendants' conduct as described below:

The Damages Class:

All persons or entities who indirectly purchased, paid, and provided reimbursement for some or all of the purchase price for fluocinonide, other than for resale, for consumption by itself, its families, or its members, employees, insureds, participants, or beneficiaries, from at least as early as August 1, 2014 through and including the date that the anticompetitive effects of Defendants' unlawful conduct ceased, in any of the following states, commonwealths, and territories: Alabama, Arizona, California, Florida, Hawaii, Iowa, Kansas, Massachusetts, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and the District of Columbia.

133. The following persons and entities are excluded from the above-described Classes:

- (a) Defendants and their counsel, officers, directors, management, employees, subsidiaries, or affiliates;
- (b) All governmental entities, except for government-funded employee benefit plans;
- (c) All persons or entities who purchased fluocinonide for purposes of resale or directly from Defendants or their affiliates;
- (d) Fully-insured health plans (plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

(e) Flat co-payers (consumers who paid the same co-payment amount for brand and generic drugs); and

(f) The judges in this case and any members of their immediate families.

134. Members of the Classes are so numerous that joinder is impracticable. Plaintiff believes that there are thousands of members of each Class.

135. Plaintiff's claims are typical of the claims of the members of the Classes. Plaintiff and members of the Classes were damaged by the same wrongful conduct by Defendants in that they paid artificially inflated prices for fluocinonide as a result of Defendants' wrongful conduct—and continue to do so.

136. Plaintiff will fairly and adequately protect and represent the interests of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the members of the Classes.

137. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with experience in class action antitrust litigation involving pharmaceutical products.

138. Questions of law and fact common to the members of the Classes predominate over questions that may affect only individual members of the Classes because Defendants have acted on grounds generally applicable to each member of the Injunctive Class and Damages Class.

139. Questions of law and fact common to members of both Classes include:

- (a) the identity of the participants in the conspiracy;
- (b) whether Defendants conspired to fix, raise, maintain, and stabilize the prices of fluocinonide;

- (c) whether Defendants conspired to rig bids for fluocinonide;
- (d) whether Defendants conspired to allocate markets or customers with respect to the fluocinonide;
- (e) whether Defendants' conduct harmed competition in the fluocinonide market;
- (f) whether Defendants' activities alleged herein have substantially affected interstate and intrastate commerce;
- (g) whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Classes in the nature of overcharges;
- (h) the amount of overcharges paid by Plaintiff and members of the Classes in the aggregate; and
- (i) the injunctive and other equitable relief needed to end Defendants' restraint and to restore competition in the fluocinonide market.

140. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs any potential difficulties in management of this class action.

141. Plaintiff knows of no special difficulty to be encountered in this action that would preclude its maintenance as a class action.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

**Violation of Sherman Act § 1, 15 U.S.C. § 1
(By Plaintiff and Injunctive Class Members Against All Defendants)**

142. Plaintiff incorporates the preceding paragraphs by reference.

143. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to rig bids and fix, raise, and maintain, the prices of, and allocated customers and markets for, fluocinonide—and continue to do so.

144. Had Defendants competed instead of conspiring to restrain trade, Plaintiff and Injunctive Class Members would have paid substantially lower prices for fluocinonide.

145. Defendants intended, and accomplished, a bid-rigging, price-fixing conspiracy and horizontal customer and market allocation for fluocinonide, which are *per se* violations of Section 1 of the Sherman Act. By their agreement, Defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act. As a result of this unreasonable restraint on competition, Plaintiff and Injunctive Class Members paid artificially inflated prices for fluocinonide—and continue to do so.

146. Plaintiff and Injunctive Class Members have suffered harm, and are continuing to suffer harm, as a result of paying higher prices for fluocinonide than they would have absent Defendants' anticompetitive conduct and continuing anticompetitive agreements. Plaintiff and Injunctive Class Members also face a continuing threat of injury from the unlawful conduct alleged in this Complaint.

147. Plaintiff and Injunctive Class Members have purchased substantial amounts of fluocinonide indirectly from Defendants.

148. Plaintiff and Injunctive Class Members seek a declaratory judgment pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) that Defendants' conduct violates Section 1 of the Sherman Act.

149. Plaintiff and Injunctive Class Members also seek equitable and injunctive relief, including disgorgement of profits, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief to ensure that the same or similar anticompetitive conduct does not reoccur in the future.

SECOND CLAIM FOR RELIEF

State Antitrust Violations (By Plaintiff and Damages Class Members Against All Defendants)

150. Plaintiff incorporates the preceding paragraphs by reference.

151. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme to rig bids and fix, raise, and maintain, the prices of, and allocated customers and markets for, fluocinonide—and continue to do so.

152. Defendants' unlawful conduct harmed Plaintiff and Damages Class Members in the manner explained above.

153. Defendants' unlawful conduct covered a sufficiently substantial percentage of the relevant market to harm competition.

154. Defendants' actions constitute horizontal market allocation and price-fixing agreements between actual and potential competitors and are illegal *per se* under state antitrust laws.

155. Defendants' supracompetitive pricing constitutes a continuing violation of the laws of the states listed below in that each purchase by Plaintiff or a member of the Damages

Class of supracompetitively priced fluocinonide caused injury to their business or property—and continues to do so.

156. Defendants' conduct violated the following state laws:

(a) Ala. Code § 6-5-60, with respect to purchases in Alabama by members of the Damages Class;

(b) Ariz. Rev. Stat. §§ 44-1401, *et seq.*, with respect to purchases in Arizona by members of the Damages Class;

(c) Cal. Bus. Code §§ 16700, *et seq.*, and Cal. Bus. Code §§ 17200, *et seq.*, with respect to purchases in California by members of the Damages Class;

(d) D.C. Code Ann. §§ 28-4501, *et seq.*, with respect to purchases in the District of Columbia by members of the Damages Class;

(e) Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Damages Class;

(f) Hawaii Code § 480, *et seq.*, with respect to purchases in Hawaii by members of the Damages Class;

(g) Iowa Code §§ 553 *et seq.*, with respect to purchases in Iowa by members of the Damages Class;

(h) Kan. Stat. Ann. §§ 50-101, *et seq.*, with respect to purchases in Kansas by members of the Damages Class;

(i) Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Damages Class;

(j) Me. Rev. Stat. Ann. 10, §§ 1101, *et seq.*, with respect to purchases in Maine by members of the Damages Class;

(k) Mich. Comp. Laws Ann. §§ 445.772, *et seq.*, with respect to purchases in Michigan by members of the Damages Class;

(l) Minn. Stat. §§ 325D.49, *et seq.*, with respect to purchases in Minnesota by members of the Damages Class;

(m) Miss. Code Ann. §§ 75-21-1, *et seq.*, with respect to purchases in Mississippi by members of the Damages Class;

(n) Neb. Code Ann. §§ 59-801, *et seq.*, with respect to purchases in Nebraska by members of the Damages Class;

(o) Nev. Rev. Stat. Ann. §§ 598A, *et seq.*, with respect to purchases in Nevada by members of the Damages Class;

(p) N.M. Stat. Ann. §§ 57-1-1, *et seq.*, with respect to purchases in New Mexico by members of the Damages Class;

(q) N.Y. Gen. Bus. L. §§ 340, *et seq.*, with respect to purchases in New York by members of the Damages Class;

(r) N.C. Gen. Stat. §§ 75-1, *et seq.*, with respect to purchases in North Carolina by members of the Damages Class;

(s) N.D. Cent. Code §§ 51-08.1-01, *et seq.*, with respect to purchases in North Dakota by members of the Damages Class;

(t) Or. Rev. Stat. §§ 6.46.705, *et seq.*, with respect to purchases in Oregon by members of the Damages Class;

(u) R.I. Gen. Laws §§ 6-36-1 *et seq.*, with respect to purchases in Rhode Island by members of the Damages Class;

(v) S.D. Codified Laws Ann. §§ 37-1, *et seq.*, with respect to purchases in South Dakota by members of the Damages Class;

(w) Tenn. Code Ann. §§ 47-25-101, *et seq.*, with respect to purchases in Tennessee by members of the Damages Class;

(x) Utah Code Ann. §§ 76-10-3101, *et seq.*, with respect to purchases in Utah by members of the Damages Class;

(y) Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Damages Class;

(z) W.Va. Code §§ 47-18-3, *et seq.*, with respect to purchases in West Virginia by members of the Damages Class; and

(aa) Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Damages Class.

157. Plaintiff and Damages Class Members have been and continue to be injured in their business or property by Defendants' antitrust violations. Their injuries consist of: (1) being denied free and open competition between competitors in the market for fluocinonide; and (2) paying higher prices for fluocinonide than they would have paid in the absence of Defendants' wrongful conduct. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

158. Plaintiff and Damages Class Members seek damages and multiple damages as permitted by law for the injuries they suffered as a result of Defendants' anticompetitive conduct.

159. Defendants are jointly and severally liable for all damages suffered by Plaintiff and Damages Class Members.

160. Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of the above-listed state antitrust laws.

THIRD CLAIM FOR RELIEF

**Unjust Enrichment
(By Plaintiff and Damages Class Members Against All Defendants)**

161. Plaintiff incorporates the preceding paragraphs by reference.

162. To the extent required, this claim is pleaded in the alternative to the other claims in this Complaint.

163. Defendants have benefited and continue to benefit from the overcharges on sales of fluocinonide made possible by the unlawful and inequitable acts alleged in this Complaint.

164. Defendants' financial benefits are traceable to Plaintiff's and Damages Class Members' overpayments for fluocinonide.

165. Plaintiff and Damages Class Members have conferred and continue to confer an economic benefit upon Defendants in the nature of profits resulting from unlawful overcharges, to the economic detriment of Plaintiff and Damages Class Members.

166. It would be futile for Plaintiff and Damages Class Members to seek a remedy from any party with whom they had or have privity of contract. Defendants have paid no consideration to anyone for any of the benefits they received indirectly from Plaintiff and Damages Class Members.

167. It would be futile for Plaintiff and Damages Class Members to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased fluocinonide, as those intermediaries are not liable and would not compensate Plaintiff and Damages Class Members for Defendants' unlawful conduct.

168. The economic benefit Defendants derived from charging monopolistic and artificially inflated prices for fluocinonide is a direct and proximate result of Defendants' unlawful practices.

169. The financial benefits Defendants derived rightfully belong to Plaintiff and Damages Class Members, who paid, and continue to pay, anticompetitive prices that inured to Defendants' benefit.

170. It would be inequitable under unjust enrichment principles under the laws of each of the states in the United States and the District of Columbia for Defendants to retain any of the overcharges Plaintiff and Damages Class Members paid for fluocinonide that were derived from Defendants' unfair and unconscionable methods, acts, and trade practices.

171. Defendants are aware of and appreciate the benefits bestowed upon them by Plaintiff and the Damages Class.

172. Defendants should be compelled to disgorge all unlawful or inequitable proceeds they received in a common fund for the benefit of Plaintiff and Damages Class Members.

173. A constructive trust should be imposed upon all unlawful or inequitable sums Defendants received that are traceable to Plaintiff and Damages Class Members.

174. Plaintiff and Damages Class Members have no adequate remedy at law.

DEMAND FOR JUDGMENT

Accordingly, Plaintiff, on its own behalf and on behalf of the proposed Classes, demands judgment that:

A. Determines that this case may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23(a), (b)(2), and (b)(3), directs that reasonable notice of this case be given to members of the Classes under Rule 23(c)(2), and declares that Plaintiff is a proper representative of the Classes;

B. Declares that Defendants' conduct violated Section 1 of the Sherman Act, the other state statutes set forth above, and the common law of unjust enrichment;

C. Enjoins Defendants from continuing their illegal activities;

D. Enters judgment against Defendants joint and severally and in favor of Plaintiff and the Classes;

E. Grants Plaintiff and the Injunctive Class equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

F. Awards the Plaintiff and the Damages Class damages and, where applicable, treble, multiple, punitive, and other damages, in an amount to be determined at trial, including interest;

G. Awards Plaintiff and the Classes their costs of suit, including reasonable attorneys' fees as provided by law; and

H. Grants further relief as necessary to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, as the Court deems just.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff, on behalf of itself and the proposed classes, demands a trial by jury on all issues so triable.

Dated: December 19, 2016

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